

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WRIGHT MEDICAL TECHNOLOGY,
INC.,

Plaintiff,

v.

PARAGON 28, INC.,

Defendant

C.A.No.

JURY TRIAL DEMANDED

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff, Wright Medical Technology, Inc., (“Wright Medical”) complains and alleges as follows against Defendant, Paragon 28, Inc. (“Defendant Paragon 28” or “Paragon 28”):

INTRODUCTION

1. Plaintiff Wright Medical is a global medical device company having its founding roots in the United States in 1950. It was then that founder Frank O. Wright discovered that people in leg casts suffered from chronic back pain caused by walking on a hard steel heel in the foot of the cast.

2. Today, Wright Medical remains a market leader in design, development, manufacture, sale and/or distribution of a variety of medical devices, systems and instruments for use in orthopedic surgical procedures, including the foot and ankle procedures.

3. Wright Medical’s medical devices, systems and instruments include, among others, various orthopedic joint and bone reconstructive surgical devices and technology that involve small joint extremities, like the foot and ankle, among others.

4. The United States Patent and Trademark Office has awarded Wright Medical numerous patents covering its inventions relating to total ankle replacement, including U.S. Patent

Nos. 9,907,561 (“561 Patent”) and 10,888,336 (“336 Patent,” and collectively with the 561 Patent, the “Asserted Patents”). The Asserted Patents are valid, enforceable and currently in full force and effect.

5. This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, 35 U.S.C. § 100, *et seq.* Defendant Paragon 28 has infringed and continues to infringe, either literally or under the doctrine of equivalents, one or more claims of the 561 Patent and 336 Patent in violation of 35 U.S.C. § 271. Defendant’s infringement will continue unless enjoined by this Court.

6. Wright Medical brings this action to stop Defendant Paragon 28 from infringing the Asserted Patents, which protect aspects of its innovative total ankle replacement technology.

THE PARTIES

7. Plaintiff Wright Medical, an indirect subsidiary of Stryker Corporation, is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business located at 1023 Cherry Road, Memphis, Tennessee 38117. Wright Medical designs, manufactures, and sells medical device products including, among other products, those for total ankle replacement.

8. Defendant Paragon 28 is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business located at 14445 Grasslands Drive, Englewood, Colorado 80112.

9. Defendant Paragon 28 directly or indirectly develops, designs, manufactures, uses, distributes, markets, offers to sell, and/or sells products in the United States, including total ankle replacement systems, devices and instruments for total ankle replacement.

JURISDICTION AND VENUE

10. This action arises under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*, which are within the subject matter jurisdiction of this federal district court under 28 U.S.C. §§ 1331 and 1338(a).

11. Defendant Paragon 28 is subject to personal jurisdiction in this District based upon its formation under the laws of the State of Delaware, its transaction of business in this District, and its use, marketing, distributing, offering for sale, and/or sales of infringing systems, devices and instruments, which has caused Wright Medical harm in this District.

12. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c), and/or 1400(b) at least because Defendant Paragon 28 resides in this District, and is subject to personal jurisdiction in this District.

FACTUAL BACKGROUND

13. Wright Medical developed innovative ankle replacement technology, including the INFINITY® Total Ankle System. Wright Medical's INFINITY® Total Ankle System was designed, *inter alia*, to provide patient mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint, for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis, as well as to correct previous ankle surgeries. Wright Medical was awarded numerous patents by patent offices around the world.

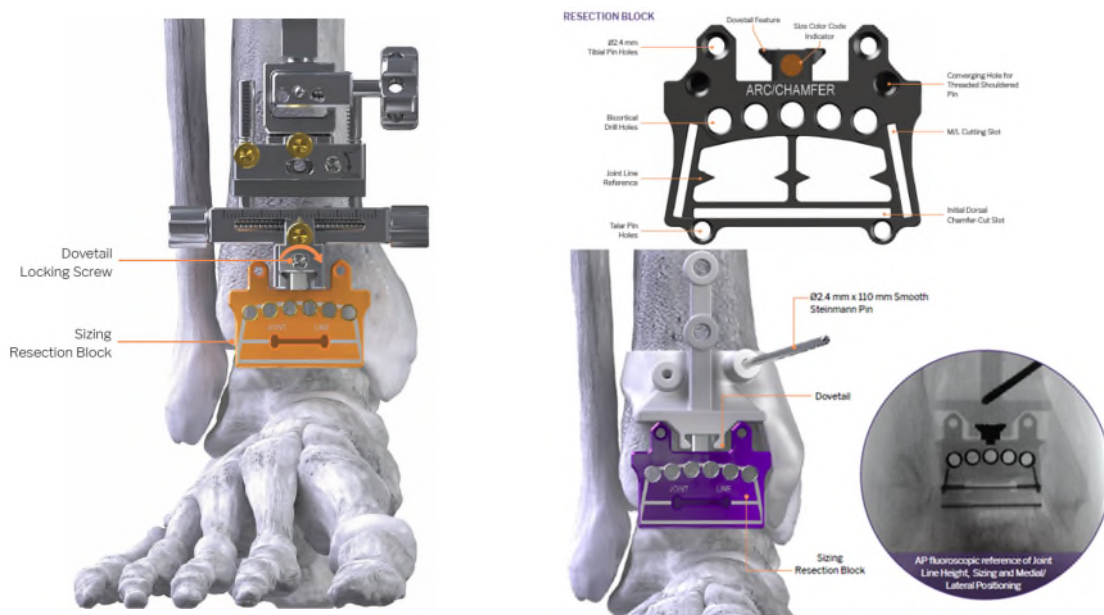
14. On March 6, 2018, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the 561 Patent, entitled "Ankle Replacement System and Method." A true and correct copy of the 561 Patent is attached as Exhibit 1 hereto.

15. On January 12, 2021, the USPTO duly and lawfully issued the 336 Patent, entitled “Ankle Replacement System and Method.” A true and correct copy of the 336 Patent is attached as Exhibit 2 hereto.

16. Wright Medical is the owner by assignment of all right, title and interest in and to the Asserted Patents as assignee.

17. Defendant Paragon 28’s business is focused on medical devices for the foot and ankle, including orthopedic devices for total ankle replacement.

18. Paragon 28 markets the APEX 3D Total Ankle Replacement System (“APEX 3D System”). The APEX 3D System includes various components including alignment guides, sizing resection blocks, resection blocks, Maven, FasTrac, and additional components.



19. Defendant provides instructions to third parties including customers, such as hospitals and doctors, on how to use the accused APEX 3D System with various publications such as instructions for use and surgical technique guides, which are available on Paragon 28’s website at www.paragon28.com. Certain surgical technique guides and instructions for use that are

publicly available for download from Paragon 28's website are attached to this Complaint as Exhibits 3-5.

20. On or about July 10, 2020, the FDA approved Defendant Paragon 28's Section 510(k) premarket notification of intent to market the APEX 3D System. On or about December 9, 2020, the FDA received Defendant Paragon 28's Section 510(k) premarket notification of intent to market ankle joint metal/polymer semi-constrained cemented prostheses that Paragon 28 referred to as the Paragon 28 Maven Patient-Specific Instrumentation. This device is described in the 510(k) summary as "patient specific surgical instrumentation" which is "intended for use with the Paragon 28 APEX 3D System." On or about January 14, 2021, the FDA approved Defendant Paragon 28's Section 510(k) premarket notification of intent to market the Paragon 28 Maven Patient-Specific Instrumentation.

21. Paragon 28, directly and/or indirectly, manufactures, markets, offers for sale, sells, uses and/or distributes in the United States total ankle replacement devices, systems, instruments, and components, which, alone or together, infringe the Asserted Patents, including, without limitation, the Paragon 28 APEX 3D System including the Maven Patient-Specific Instrumentation and FasTrac.

22. Various websites indicate that doctors have used and continue to use the APEX 3D System, constituting direct infringement. (*See, e.g.,* <https://www.prnewswire.com/news-releases/paragon-28-inc-conducts-the-first-total-ankle-joint-replacement-surgery-utilizing-laser-alignment-technology-301289757.html>.)

23. On information and belief, at all relevant times to this action, Paragon 28 knew of and/or was willfully blind to the Asserted Patents. For example, Paragon 28 referenced the 561 patent as well as patents related to the 561 and 336 Patents, including the parent to the 336 Patent,

during prosecution of Paragon 28's own patent applications related to total ankle replacement. A surgical technique guide for one of Wright Medical's products has also been cited in an international search report in a PCT application filed by Paragon 28.

24. In addition, on information and belief, a number of former Wright Medical employees have been and/or are employed by Paragon 28, including employees associated with the foot and ankle and total ankle replacement divisions. Various of the former Wright Medical employees have knowledge of Wright Medical's INFINITY® Total Ankle System and one or both of the Asserted Patents and related patents covering the INFINITY® Total Ankle System, which was gained through their employment by Wright Medical. For example, a vice president for Paragon 28's total ankle replacement division, which includes the APEX 3D System, was formerly a director of marketing for foot and ankle (including for INFINITY® Total Ankle Replacement products) at Wright Medical. Various of Paragon 28's sales personnel for total ankle replacement products (including APEX 3D Systems) were formerly employed by Wright Medical and sold INFINITY® Total Ankle Replacement systems. In addition, Paragon 28 consulted with medical and/or medical design individuals who were former consultants to Wright Medical for the INFINITY® Total Ankle Replacement System. Various of these employees and/or consultants had knowledge of Wright Medical's INFINITY® Total Ankle System and one or more of the Asserted Patents and related patents covering the INFINITY® Total Ankle System while employed by Wright Medical.

25. Other facts further indicate Paragon 28 had knowledge of the Asserted Patents. Notably, Wright Medical and Paragon 28 are also involved in other disputes regarding Paragon 28's alleged infringement and misappropriation of Wright Medical trade secrets relating to foot and ankle bone plating technology, for example, in the United States District Court for the District

of Colorado (Civ. Action No. 18-cv-00691). Wright Medical and Defendant Paragon 28 are direct and active competitors. The Asserted Patents are also identified on Wright Medical's virtual patent marking page on Wright Medical's website (<https://www.wright.com/corporate/patent-information>) for Wright Medical's INFINITY® Total Ankle System. And finally, Paragon 28 has additional knowledge of the Asserted Patents upon receipt of this complaint.

26. Wright Medical has suffered, and continues to suffer, damages as a result of Defendant Paragon 28's infringement of the Asserted Patents.

FIRST CAUSE OF ACTION
(Infringement of the 561 Patent)

27. Wright Medical incorporates the foregoing paragraphs by reference as though set forth fully herein.

28. Defendant Paragon 28 has infringed and continues to infringe at least claim 13 of the 561 patent by inducing infringement pursuant to 35 U.S.C. § 271(b) and/or contributing to infringement pursuant to 35 U.S.C. § 271(c).

29. On information and belief, Defendant Paragon 28's customers directly infringe the 561 patent. For example, when the APEX 3D System is offered for sale and/or sold to Paragon 28's customers, such as hospitals and doctors, those customers infringe at least independent claim 13 of the 561 Patent through the use of the APEX 3D System.

30. On information and belief, use of the APEX 3D System meets every limitation, literally or under the doctrine of equivalents, of at least independent Claim 13 of the 561 Patent.

31. Claim 13 of the 561 Patent recites:

A method, comprising:

coupling a drill guide to a first bone, wherein the drill guide comprises a plurality of guide holes;

forming a plurality of pilot holes in the first bone through the plurality of guide holes of the drill guide, wherein the pilot holes define proximal corners of a resection cut to be made in the first bone;

removing the drill guide from the first bone;

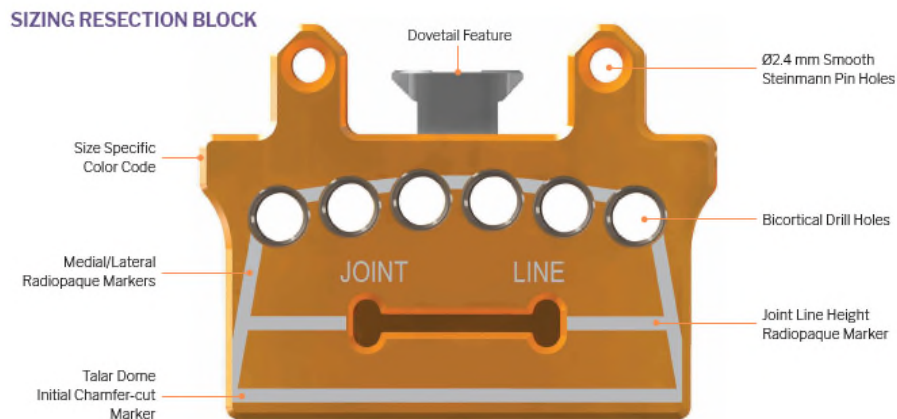
coupling a cutting guide to the first bone, wherein the cutting guide defines at least two slots for guiding a surgical tool to form one or more resectioning cuts;

cutting the one or more resectioning cuts to form a resectioned joint space between the first bone and a second bone;

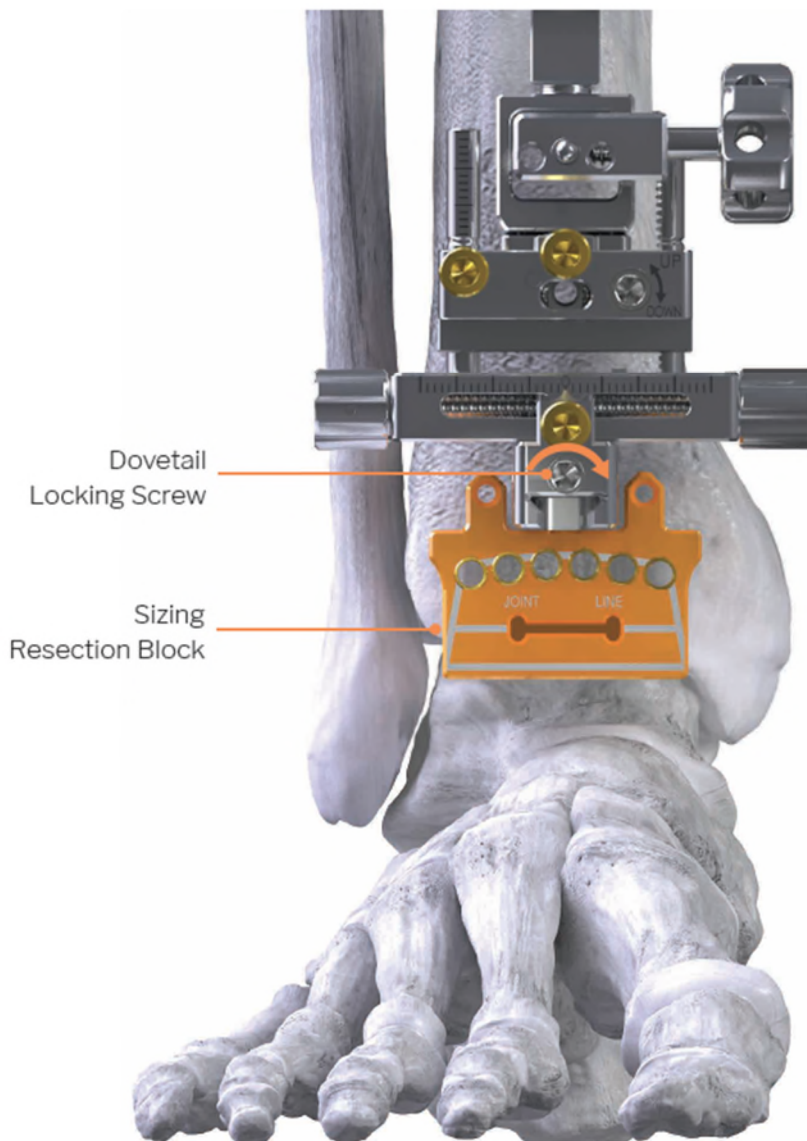
inserting a first trial into the resectioned joint space, wherein the first trial is seated flush against the first bone, and wherein the first trial is removably coupled to the first bone; and

performing a trial reduction to determine a height and a position of one or more implants.

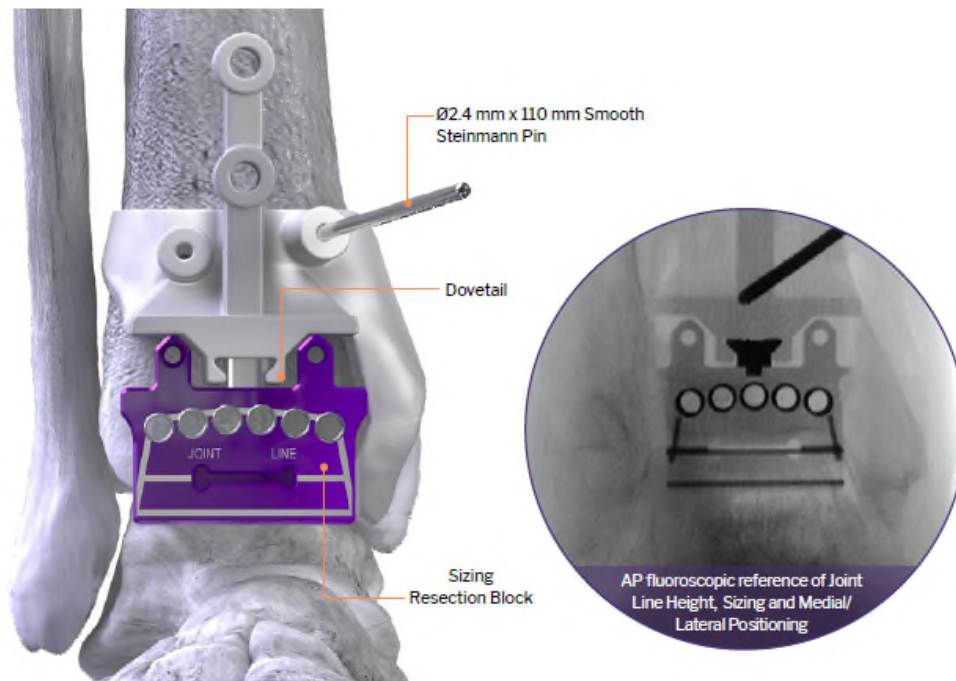
32. The use of the APEX 3D System practices a “method comprising: coupling a drill guide to a first bone, wherein the drill guide comprises a plurality of guide holes.” For example, the APEX 3D System Surgical Technique Guides, including for a Traditional Alignment Guide, a Maven Patient-Specific Instrumentation Guide, and FasTrac of the APEX 3D System, depict and instruct:



(Ex. 3, Apex 3D Total Ankle Replacement Surgical Technique Guide (P10-STG-0001-Rev-A), retrieved from <https://paragon28.com/products/apex-3d-tar/> (“APEX 3D Surgical Technique Guide”), at 8.)



(Ex. 3, APEX 3D System Surgical Technique Guide, at 9.)



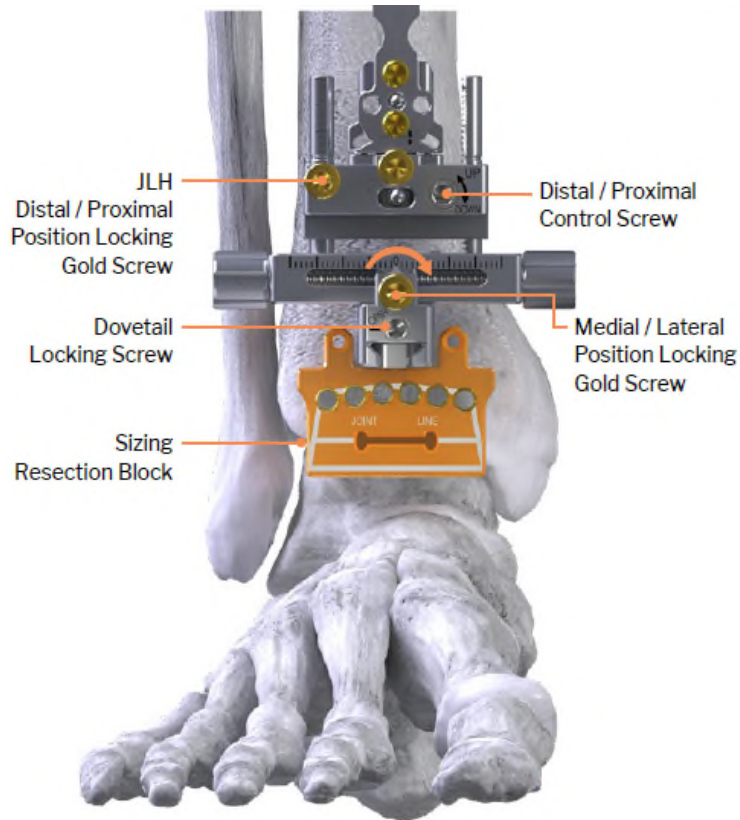
**POSITIONING CONFIRMATION
JOINT LINE HEIGHT, SIZING & MEDIAL / LATERAL**

- Attach the size-matched Sizing Resection Block [P10-942-SZxx], as depicted in the surgeon-approved SPCR, to the Guide's integrated dovetail connection.
- With the size-matched Sizing Resection Block attached to the PSI Guide's dovetail connection, under an AP fluoroscopic view and against the surgeon-approved SPCR verify:
 - Joint Line Height
 - Sizing, interchanging Sizing Resection Block options as necessary
 - Medial / Lateral Positioning

(Ex. 4, Apex 3D Total Ankle Replacement Powered by MAVEN Patient-Specific Instrumentation

Surgical Technique Guide (P10-STG-002-Rev-B), retrieved from

<https://paragon28.com/products/apex-3d-tar/>, (“Maven Surgical Technique Guide”), at 9.)



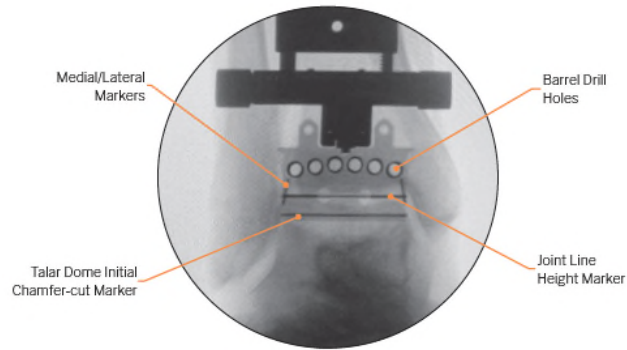
(Ex. 5, FasTrac Surgical Technique Guide (P10-STG-0003-Rev-B), retrieved from <https://paragon28.com/products/apex-3d-tar/> (“FasTrac Surgical Technique Guide”), at 9.)

33. The use of the APEX 3D System practices “forming a plurality of pilot holes in the first bone through the plurality of guide holes of the drill guide, wherein the pilot holes define proximal corners of a resection cut to be made in the first bone.” For example, the APEX 3D System Surgical Technique Guide instructs:

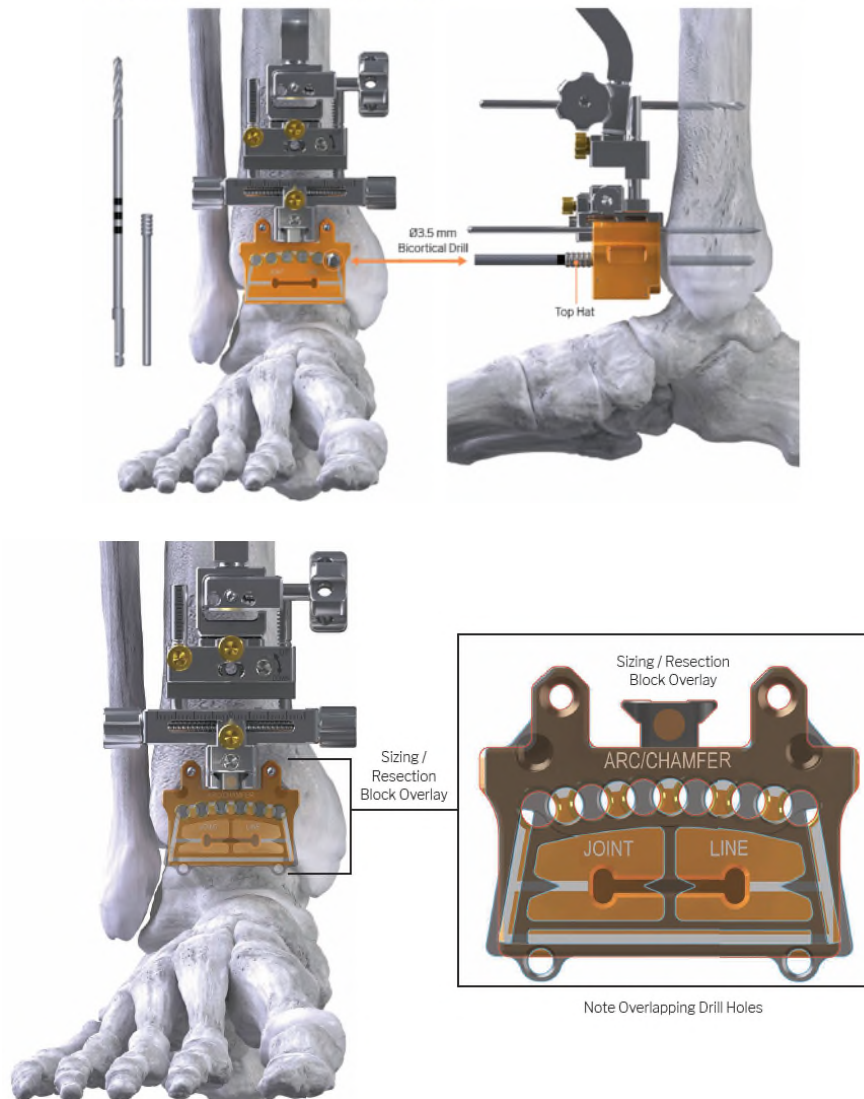
Utilizing the Ø3.5 mm ARC Tibia Resection Drill [P10-942-3513], drill bicortically into the medial most corner hole of the Sizing Resection Block, ensuring drill clears the posterior cortex, but does not penetrate beyond. . . . Perform sequential drilling of the additional holes.

(Ex. 3, APEX 3D System Surgical Technique Guide, at 14.)

34. In addition, for example, the following images appear in the APEX 3D System Surgical Technique Guide.



ARC TIBIA BONE - PREPARATION



(Ex. 3, APEX 3D System Surgical Technique Guide, at 14-15; *see* Ex. 4, Maven Surgical Technique Guide, at 14; Ex. 5, FasTrac Surgical Technique Guide, at 11.)

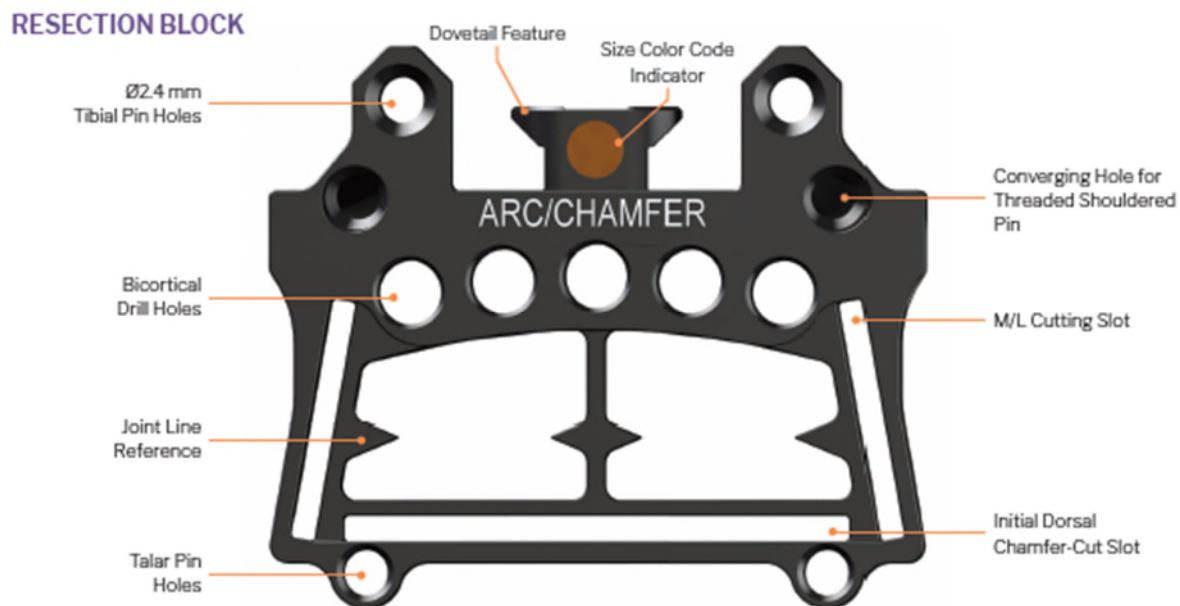
35. The use of the APEX 3D System practices “removing the drill guide from the first bone.” For example, the APEX 3D System Surgical Technique Guide instructs:

SEQUENTIAL DRILLING

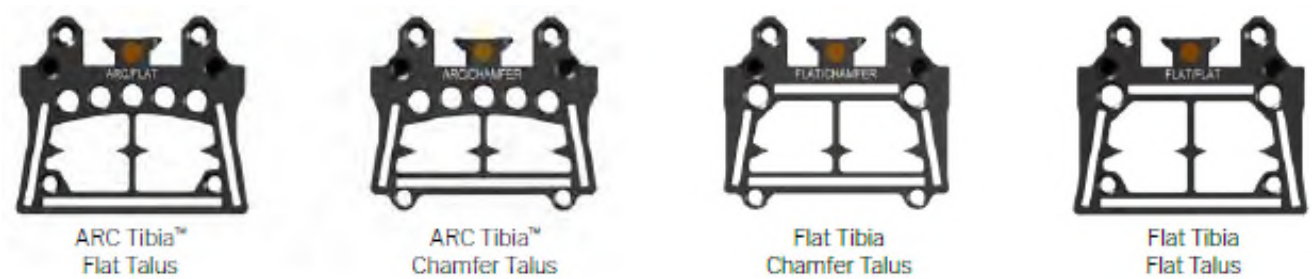
- Perform sequential drilling of the additional holes.
- Rotate the silver “OPEN” screw and remove the Sizing Block and Top Hat.

(Ex. 3, APEX 3D Surgical Technique Guide, p. 14; *see* Ex. 4, Maven Surgical Technique Guide, at 14; Ex. 5, FasTrac Surgical Technique Guide, at 11.)

36. The use of the APEX 3D System practices “coupling a cutting guide to the first bone, wherein the cutting guide defines at least two slots for guiding a surgical tool to form one or more resectioning cuts,” for example:



(Ex. 3, APEX 3D System Surgical Technique Guide, at 15.)



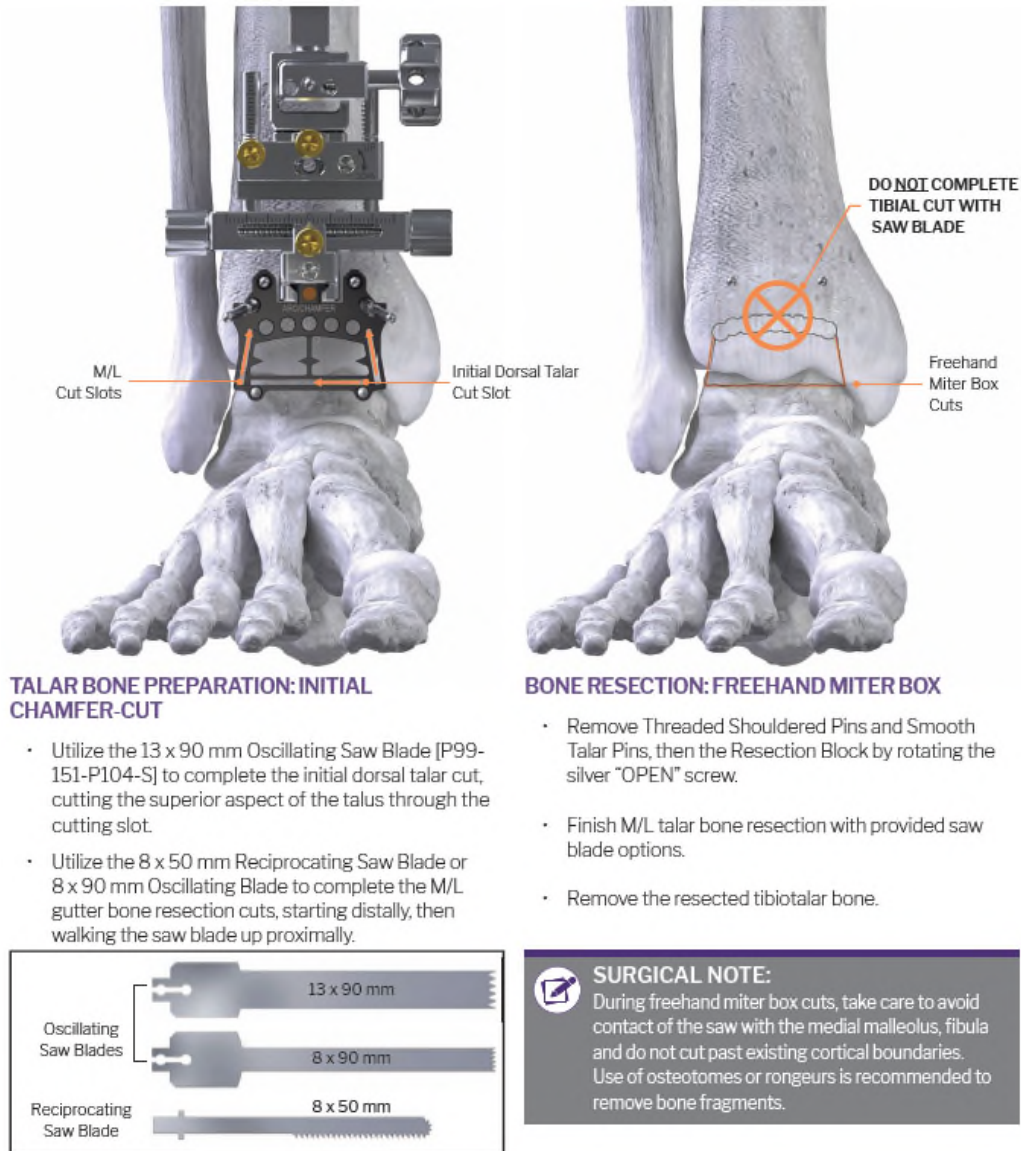
(Ex. 6, Apex 3D Total Ankle Replacement System Brochure (P10-STM-0001-Rev-A), retrieved from <https://paragon28.com/products/apex-3d-tar/> (“APEX 3D Brochure”), at 4.)

37. Further, the APEX 3D System Surgical Technique Guide depicts and instructs:

TIBIAL BONE PREPARATION – RESECTION BLOCK

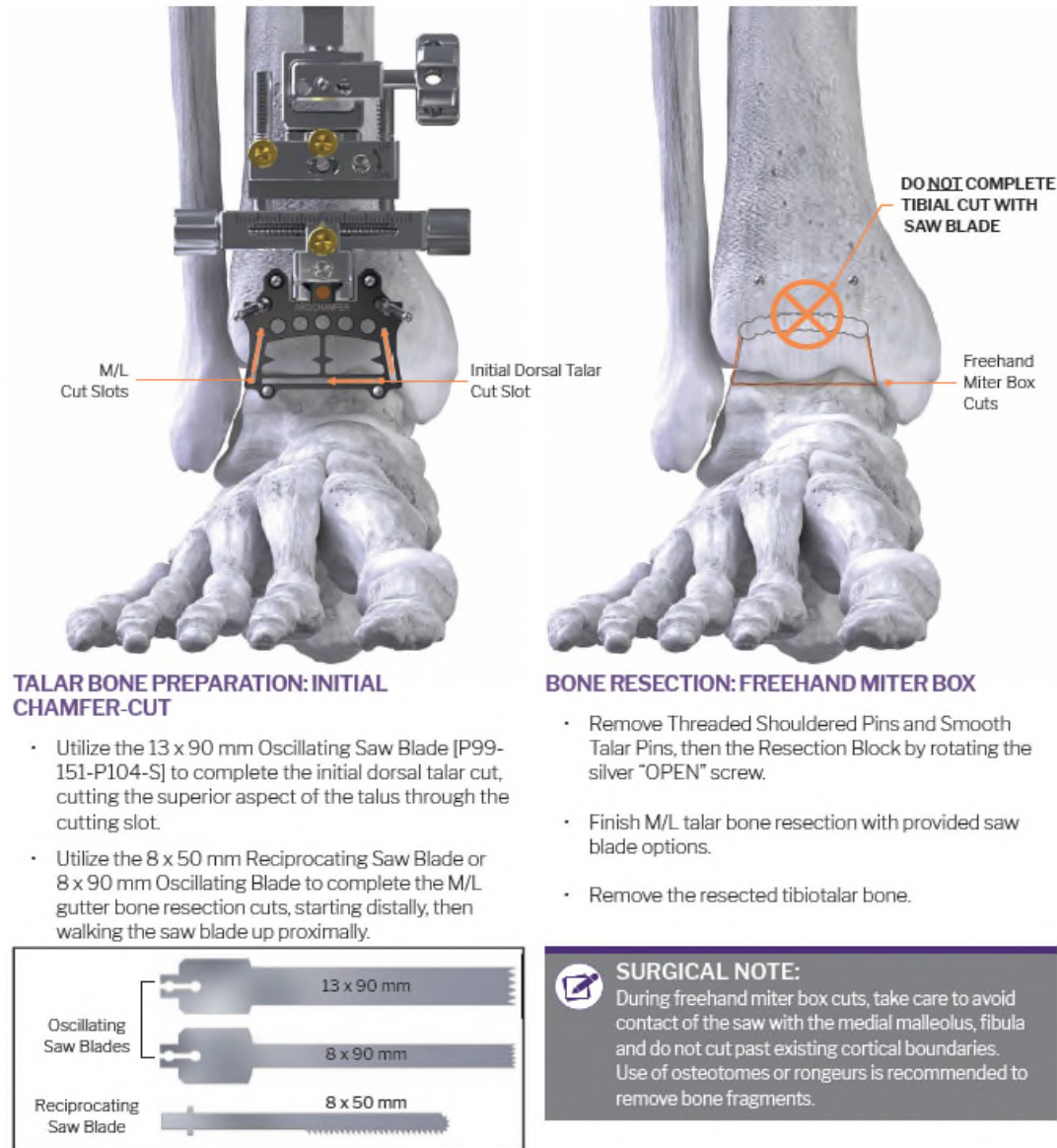
- Slide the proximal portion of the Resection Block over the two (2) M/L Ø2.4 mm guide pins and into the dovetail connection of the Alignment Construct and lock in place.

(Ex. 3, APEX 3D System Surgical Technique Guide, at 16.)

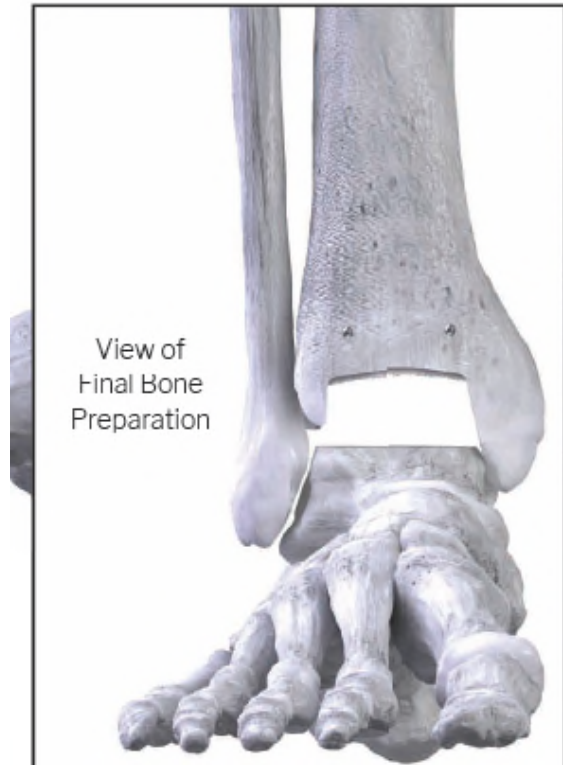


(Ex. 3, APEX 3D System Surgical Technique Guide, at 18; *see* Ex. 4, Maven Surgical Technique Guide, at 14; Ex. 5, FasTrac Surgical Technique Guide, at 11.)

38. The use of the APEX 3D System practices “cutting the one or more resectioning cuts to form a resectioned joint space between the first bone and a second bone.” For example, the APEX 3D System Surgical Technique Guides depict and instruct:



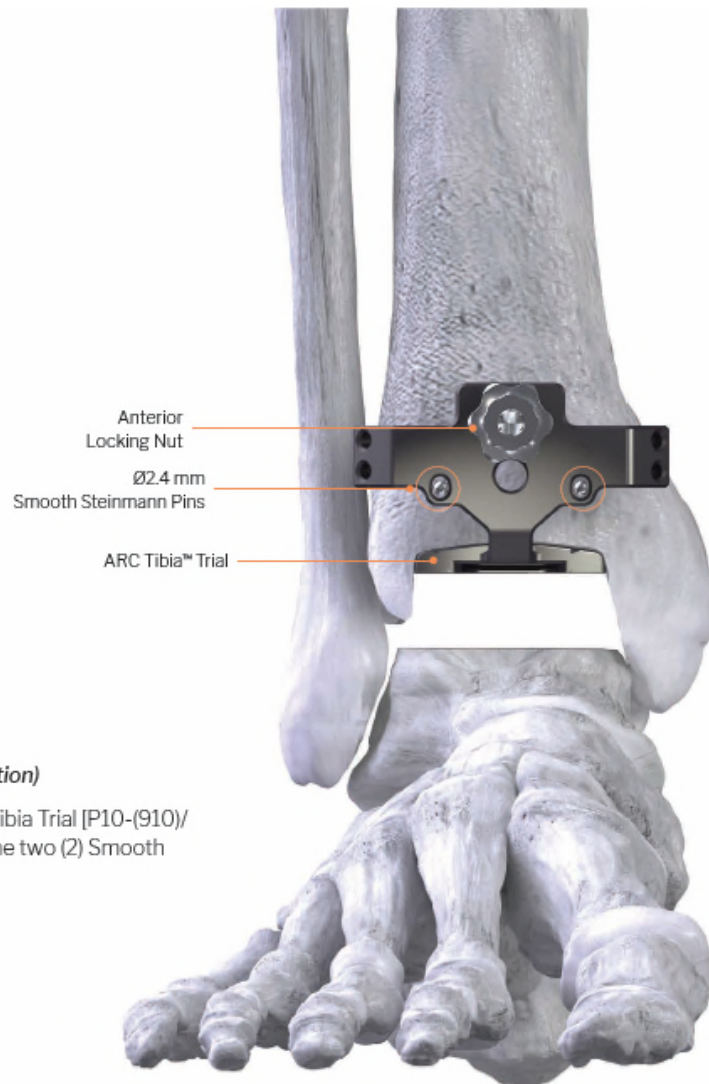
(Ex. 3, APEX 3D System Surgical Technique Guide, at 18, 21; *see* Ex. 4, Maven Surgical Technique Guide, at 14; Ex. 5, FasTrac Surgical Technique Guide, at 11.)



(Ex. 3, APEX 3D System Surgical Technique Guide, at 18, 21; *see* Ex. 4, Maven Surgical Technique Guide, at 14; Ex. 5, FasTrac Surgical Technique Guide, at 11.)

39. The use of the APEX 3D System practices “inserting a first trial into the resectioned joint space, wherein the first trial is seated flush against the first bone, and wherein the first trial is removably coupled to the first bone.” For example, the APEX 3D System Surgical Technique Guides depict and instruct:

TIBIAL TRIALING



TIBIAL TRIAL POSITIONING

(Follow Similar Steps for Flat-cut Option)

- Utilizing the size matched ARC Tibia Trial [P10-(910)/ (911)-TBxx], by hand, slide over the two (2) Smooth Steinmann Pins already in place.

(Ex. 3, APEX 3D System Surgical Technique Guide, at 24; *see* Ex. 4, Maven Surgical Technique Guide, at 24-27; Ex. 5, FasTrac Surgical Technique Guide, at 11.)

SECURE TIBIAL TRIAL

(Follow Similar Steps for Flat-cut Option)

- By hand, place two (2) Ø2.4 mm x 50 mm Threaded Shouldered Pins into a set of the offset converging pin holes located on the medial and lateral aspect of the Tibial Trial.
- Ensure that either both laser marked pin holes are used together, or non-laser marked pin holes are used together.
- Connect to power and advance stopping before the shoulder engages the trial. (DO NOT FULLY SEAT UNDER POWER)
- By hand, secure the pin against trial using the provided T-Handle.
- Remove the Distractor, re-check Tibial Trial position under lateral fluoroscopy to confirm position and fit.

TIBIAL & TALAR TRIAL - CONSTRUCT REMOVAL

- Remove the Poly Trial using the Poly Handling Tool.
- Remove the Shouldered Pins from the Tibial Trial.
- Remove the Tibial Trial.
- Remove the Ø2.4 mm smooth Steinmann Pins from Tibial Trial.
- Remove the fixation Pins from Talar Trial.
- Remove the Talar Trial using the Talar Handling Tool

(Ex. 3, APEX 3D System Surgical Technique Guide, at 24-26, 43; *see* Ex. 4, Maven Surgical Technique Guide, at 24-27; Ex. 5, FasTrac Surgical Technique Guide, at 11.)

40. The use of the APEX 3D System practices “performing a trial reduction to determine a height and a position of one or more implants.” For example, the APEX 3D System Surgical Technique Guides depict and instruct:

TIBIAL TRIAL – SIZING EVALUATION

- Under a lateral fluoroscopic view determine tibia implant length.
- With the Parallel Distractor loosely retracted in position, fine tune the anterior position of the tibial trial by adjusting the AP positioning bolt.
- Once appropriate positioning has been achieved, secure the Tibial Trial's position by advancing the anterior locking nut until flush against trial.

(Ex. 3, APEX 3D System Surgical Technique Guide, at 26; *see* Ex. 4, Maven Surgical Technique Guide, at 14; Ex. 5, FasTrac Surgical Technique Guide, at 11.)

CHAMFER TALUS & POLY TRIAL PLACEMENT

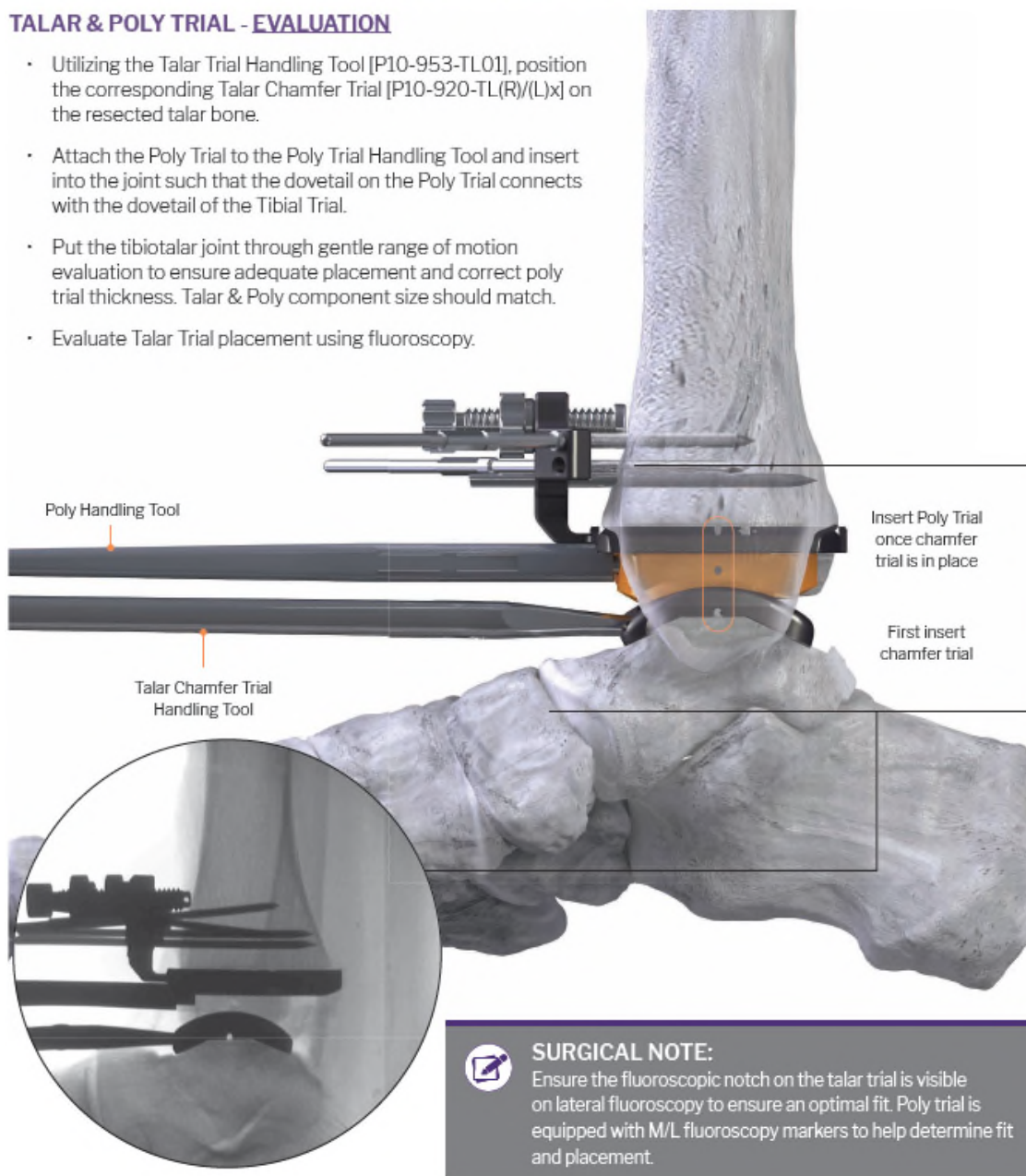


(Ex. 3, APEX 3D System Surgical Technique Guide, at 38; *see* Ex. 4, Maven Surgical Technique Guide, at 14, 26; Ex. 5, FasTrac Surgical Technique Guide, at 11.)

CHAMFER-CUT: TALAR & POLY TRIAL EVALUATION

TALAR & POLY TRIAL - EVALUATION

- Utilizing the Talar Trial Handling Tool [P10-953-TL01], position the corresponding Talar Chamfer Trial [P10-920-TL(R)/(L)x] on the resected talar bone.
- Attach the Poly Trial to the Poly Trial Handling Tool and insert into the joint such that the dovetail on the Poly Trial connects with the dovetail of the Tibial Trial.
- Put the tibiotalar joint through gentle range of motion evaluation to ensure adequate placement and correct poly trial thickness. Talar & Poly component size should match.
- Evaluate Talar Trial placement using fluoroscopy.



(Ex. 3, APEX 3D System Surgical Technique Guide, at 39; *see* Ex. 4, Maven Surgical Technique Guide, at 14; Ex. 5, FasTrac Surgical Technique Guide, at 11.)

41. On information and belief, Paragon 28 has directed and directs third parties, including customers and other users, in the United States, to use the APEX 3D System, which directly infringe the 561 Patent and which Paragon 28 knows infringe the 561 patent. Defendant

provides instructions to third parties including customers, such as hospitals and doctors, on how to use the accused APEX 3D System in a manner that Paragon knows practices the claimed inventions. For example, as described above, Defendant's instructions for use and surgical technique guides describe how to use the APEX 3D System. The instructions for use and surgical technique guides highlight the infringing features to customers, such as hospitals and doctors. Example surgical technique guides and instructions for use are attached to this Complaint as Exhibits 3-5.

42. On information and belief, in violation of 35 U.S.C. § 271(b), Defendant Paragon 28 specifically intends to induce infringement of the 561 patent by its customers and users of the APEX 3D System and has knowledge that the inducing acts would cause infringement or was willfully blind to the possibility that their inducing acts would cause infringement.

43. On information and belief, at all relevant times, Defendant Paragon 28 knew or was willfully blind to how the APEX 3D System infringes the 561 Patent. Paragon 28 has been and is actively inducing infringement of the 561 Patent by actively and knowingly inducing third parties such as customers, including, e.g., hospitals and doctors, to commit acts that Defendant knows constitute infringement of the 561 Patent.

44. On information and belief, Defendant Paragon 28 actively and knowingly intended to aid, abet, direct, encourage, or otherwise instruct such third parties by Paragon 28's offer for sale and sale of the APEX 3D Systems and instructions to infringe the 561 patent. Paragon 28 encourages infringement by customers at least by providing product instructions for use and surgical technique guides, as discussed above, that instruct users on how to use the APEX 3D System in an infringing manner. Paragon 28 has and continues to specifically intend to induce infringement of the 561 Patent.

45. On information and belief, despite Defendant Paragon 28's knowledge of the 561 Patent and knowledge that customers will necessarily infringe the 561 Patent when the APEX 3D System is used as instructed, Paragon 28 has and continues to encourage infringement.

46. Defendant Paragon 28 also contributes to infringement of the 561 Patent by Paragon 28's customers in violation of 35 U.S.C. §271(c). On information and belief, Paragon 28 was aware of the 561 Patent at all relevant times, as discussed above. Paragon 28 sells and offers for sale within the United States the APEX 3D System knowing that it constitutes a material part of the claimed inventions of the 561 Patent, knowing that the APEX 3D System is especially made or especially adapted for use in infringing the 561 Patent, and knowing that the APEX 3D System is not a staple article or commodity of commerce suitable for substantial non-infringing use.

47. Unless enjoined by this Court, Defendant Paragon 28 will continue to infringe the 561 Patent and as a direct result Wright Medical will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Wright Medical is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

48. Wright Medical has suffered and will continue to suffer damage as a direct and proximate result of Defendant Paragon 28's infringement of the 561 Patent. Thus, in addition to injunctive relief, Wright Medical is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

49. On information and belief, the infringement of the 561 Patent by Defendant Paragon 28 has been and continues to be willful and deliberate.

50. Defendant Paragon 28 has committed and continues to commit all of the above acts of infringement without license or authorization from Wright Medical.

51. On information and belief, Defendant Paragon 28 has had knowledge of the 561 Patent and knowledge that use of the APEX 3D System is covered by the 561 Patent. Paragon 28 has copied and made, offered for sale and sold the APEX 3D System knowing of the risk of infringement and/or in view of a risk of infringement that was sufficiently obvious that it should have been known to Paragon 28. Paragon 28's infringing actions have been and continue to be willful, entitling Wright Medical to increased damages under 35 U.S.C. § 284, and further qualifies this action as an exceptional case supporting an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

SECOND CAUSE OF ACTION
(Infringement of the 336 Patent)

52. Wright Medical incorporates the foregoing paragraphs by reference as though set forth fully herein.

53. Defendant Paragon 28 has directly infringed, and continues to directly infringe, literally or under the doctrine of equivalents, at least Claims 1-6 and 8-11 of the 336 Patent by making, using, offering to sell, and/or selling within the United States, and/or by importing into the United States, certain products, including but not limited to the APEX 3D System, and contributed to and/or induced infringement of the 336 Patent by others, including customers such as hospitals and doctors.

54. For example, on information and belief, the APEX 3D System meets every limitation, literally or under the doctrine of equivalents, of at least Claims 1-6 and 8-11 of the 336 Patent, and Defendant Paragon 28's making, using, offering for sale, selling and/or importing into the United States the APEX 3D System directly infringes at least Claims 1-6 and 8-11 of the 336 Patent under 35 U.S.C. § 271(a).

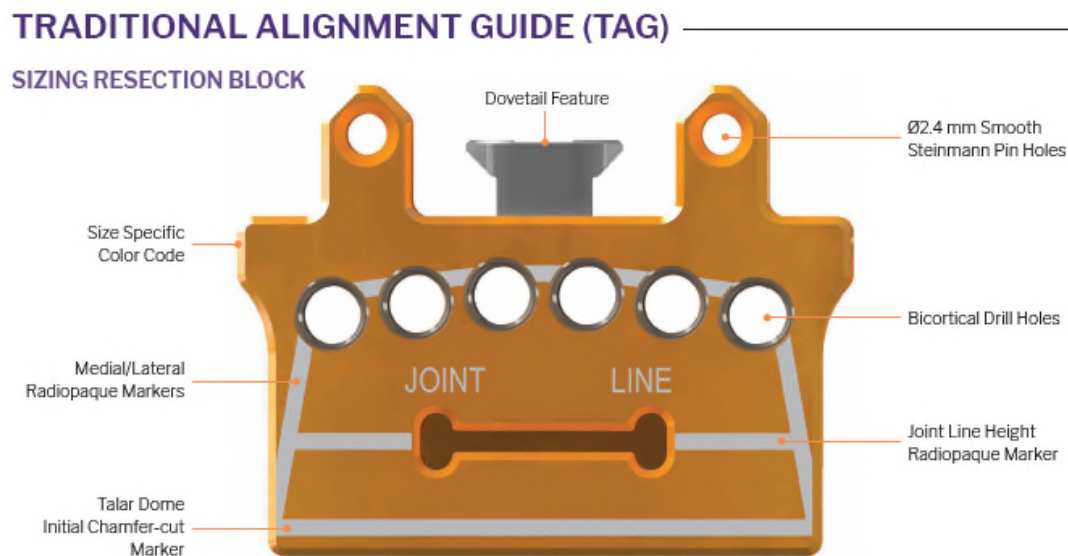
55. Claim 1 of the 336 Patent recites:

1. A surgical guide, comprising:

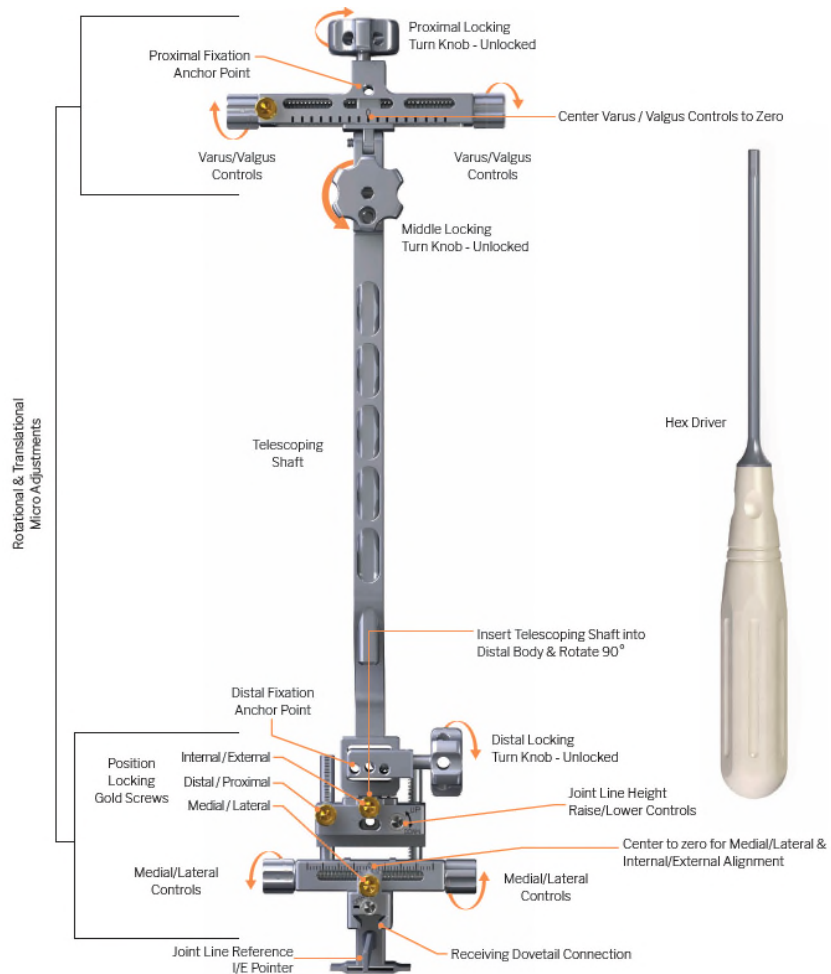
a body configured to be inserted into a block that is configured to be coupled to a bone, the body defining at least a first guide hole and a second guide hole, wherein the first and second guide holes are sized and configured to receive a first surgical tool for forming pilot holes in the bone and wherein the body comprises radiopaque surfaces defining the first and second guide holes; and

a sizing pattern coupled to the body, the sizing pattern having a size and being coupled to the body at a location for estimating resectioning cuts to be made to the bone, wherein the sizing pattern comprises at least two radiopaque lines each comprising a length dimension configured to provide a fluoroscopic cue for positioning the body.

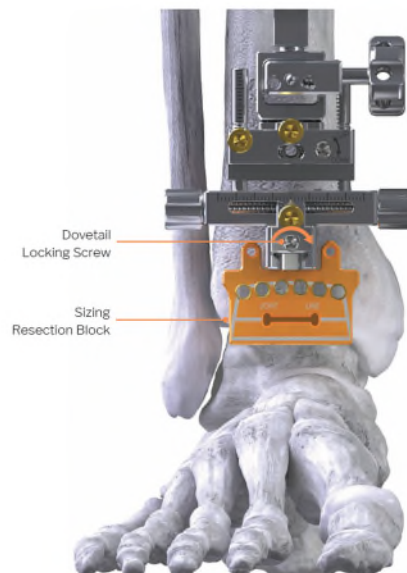
56. The APEX 3D System includes “[a] surgical guide, comprising a body configured to be inserted into a block that is configured to be coupled to a bone.” For example, the APEX 3D System Surgical Technique Guides depict and instruct:



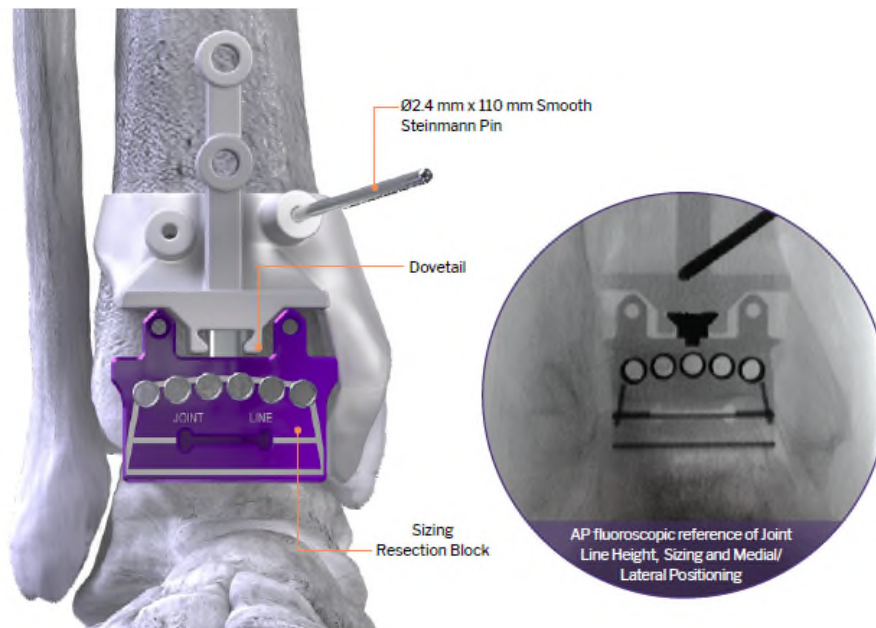
(Ex. 3, APEX 3D System Surgical Technique Guide, at 8.)



(Ex. 3, APEX 3D System Surgical Technique Guide, at 4.)



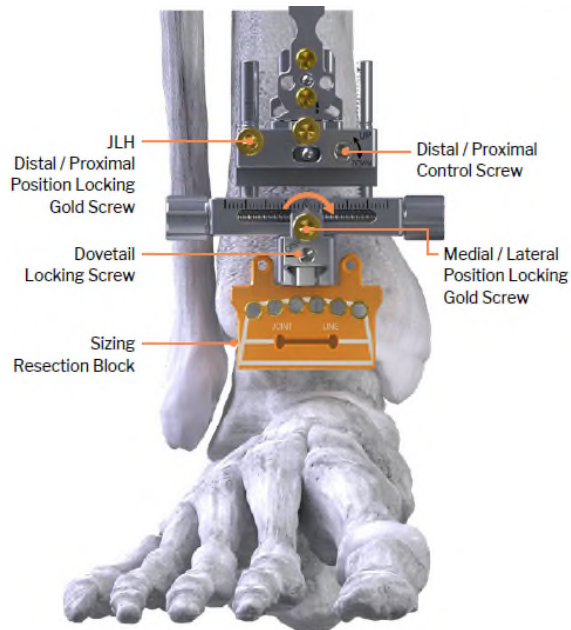
(Ex. 3, APEX 3D System Surgical Technique Guide, at 9.)



**POSITIONING CONFIRMATION
JOINT LINE HEIGHT, SIZING & MEDIAL / LATERAL**

- Attach the size-matched Sizing Resection Block [P10-942-SZxx], as depicted in the surgeon-approved SPCR, to the Guide's integrated dovetail connection.
- With the size-matched Sizing Resection Block attached to the PSI Guide's dovetail connection, under an AP fluoroscopic view and against the surgeon-approved SPCR verify:
 - Joint Line Height
 - Sizing, interchanging Sizing Resection Block options as necessary
 - Medial / Lateral Positioning

(Ex. 4, Maven Surgical Technique Guide, at 9.)



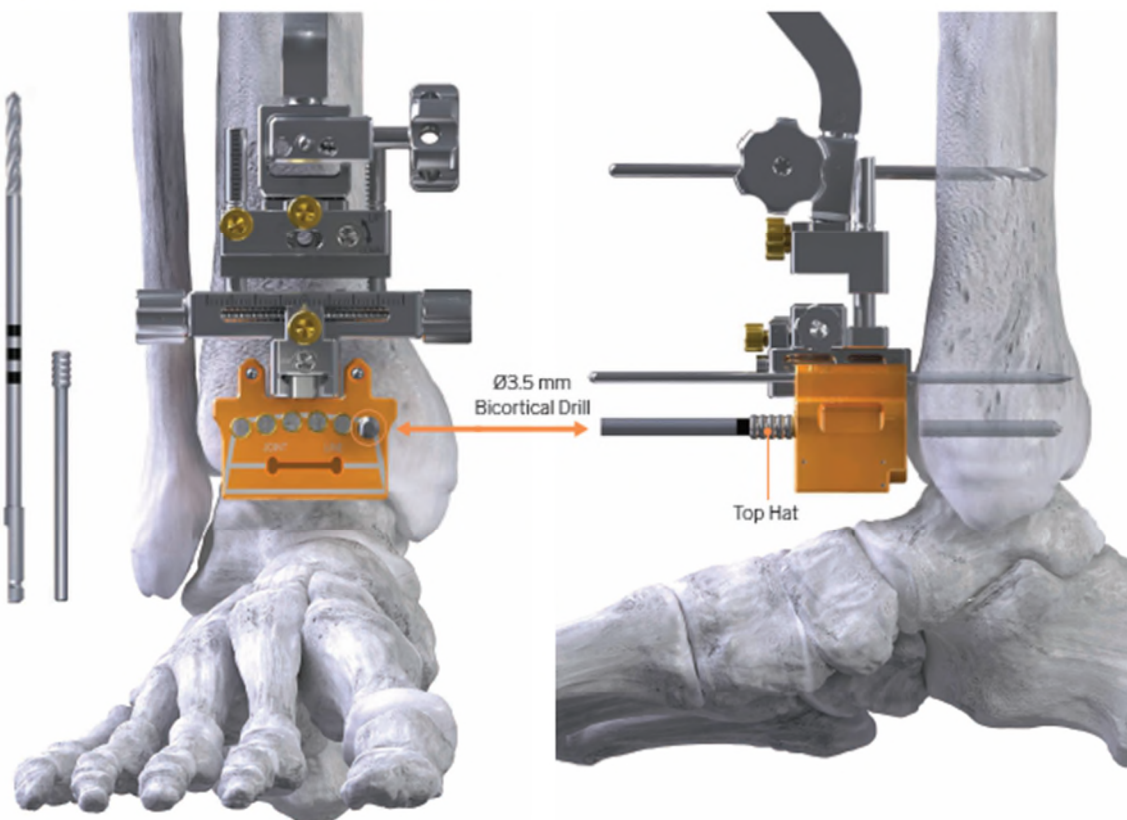
(Ex. 5, FasTrac Surgical Technique Guide, at 10.)

- Insert the Sizing Resection Block [P10-942-SZxx], based on preoperative planning sizing requirements, into the FasTrac™ alignment construct's dovetail connection.

(Ex. 5, FasTrac Surgical Technique Guide, at 8.)

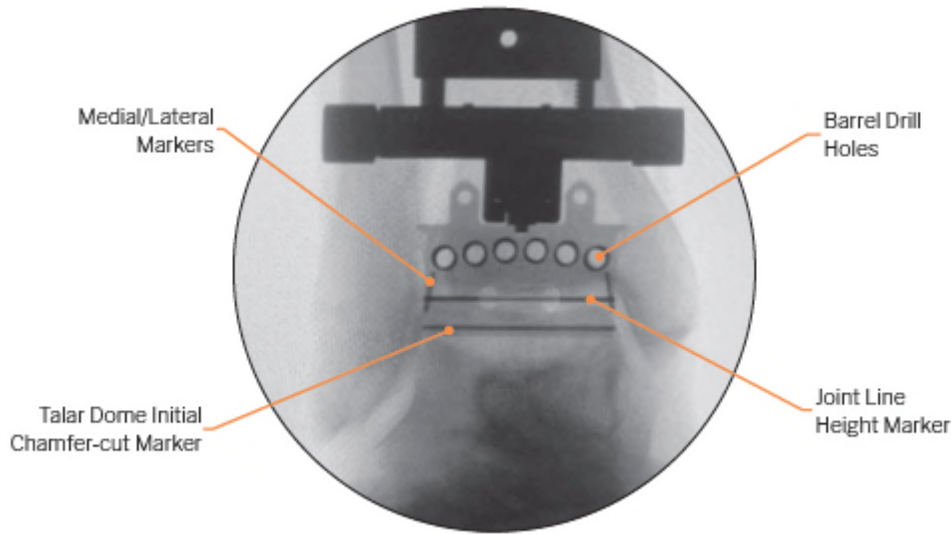
57. The APEX 3D System also includes “the body defining at least a first guide hole and a second guide hole, wherein the first and second guide holes are sized and configured to receive a first surgical tool for forming pilot holes in the bone,” for example, as shown and described in the APEX 3D System Surgical Technique Guides:

ARC TIBIA BONE - PREPARATION



(Ex. 3, APEX 3D System Surgical Technique Guide, at 13-14; *see* Ex. 4, Maven Surgical Technique Guide, at 14; Ex. 5, FasTrac Surgical Technique Guide, at 11.)

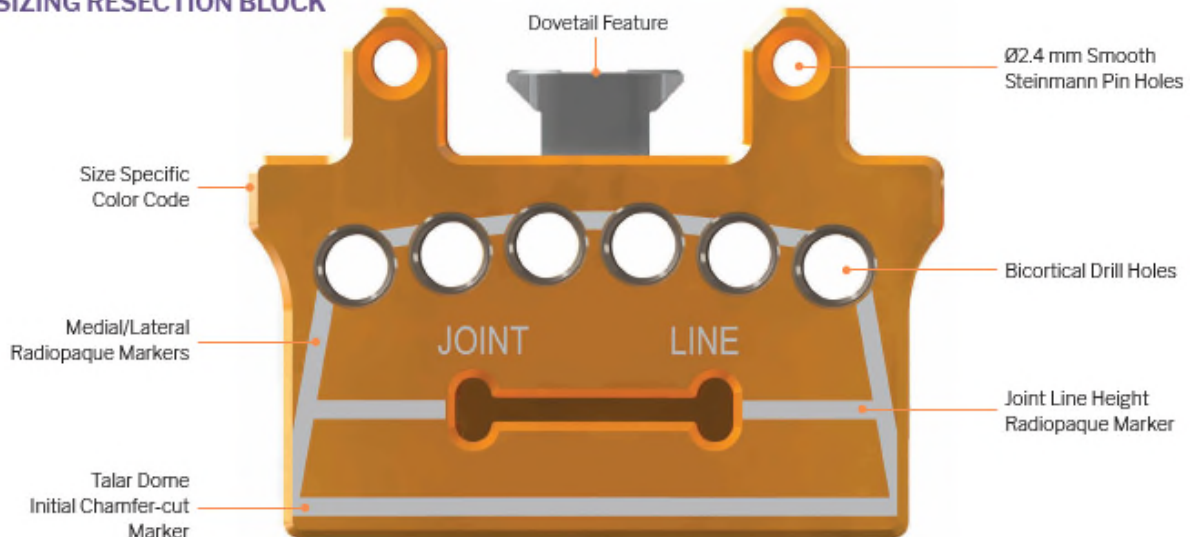
58. The APEX 3D System also includes “wherein the body comprises radiopaque surfaces defining the first and second guide holes,” for example:



(Ex. 3, APEX 3D System Surgical Technique Guide, at 8.)

TRADITIONAL ALIGNMENT GUIDE (TAG)

SIZING RESECTION BLOCK

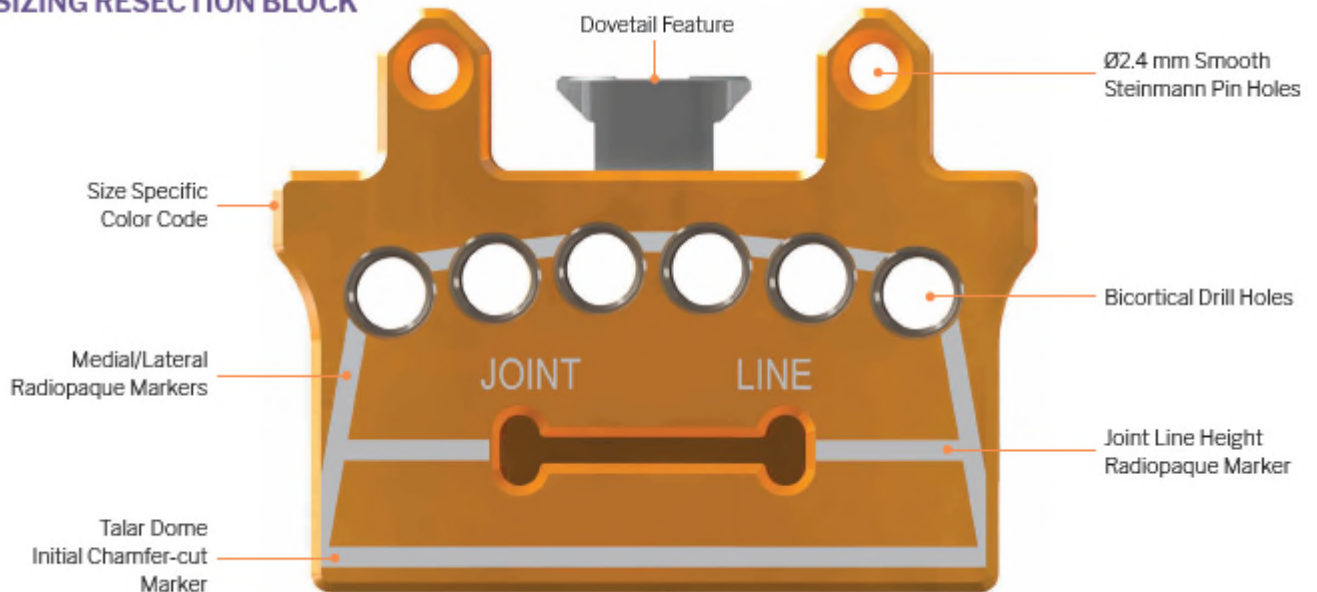


(Ex. 3, APEX 3D System Surgical Technique Guide, at 8; *see* Ex. 4, Maven Surgical Technique Guide, at 7; Ex. 5, FasTrac Surgical Technique Guide, at 4.)

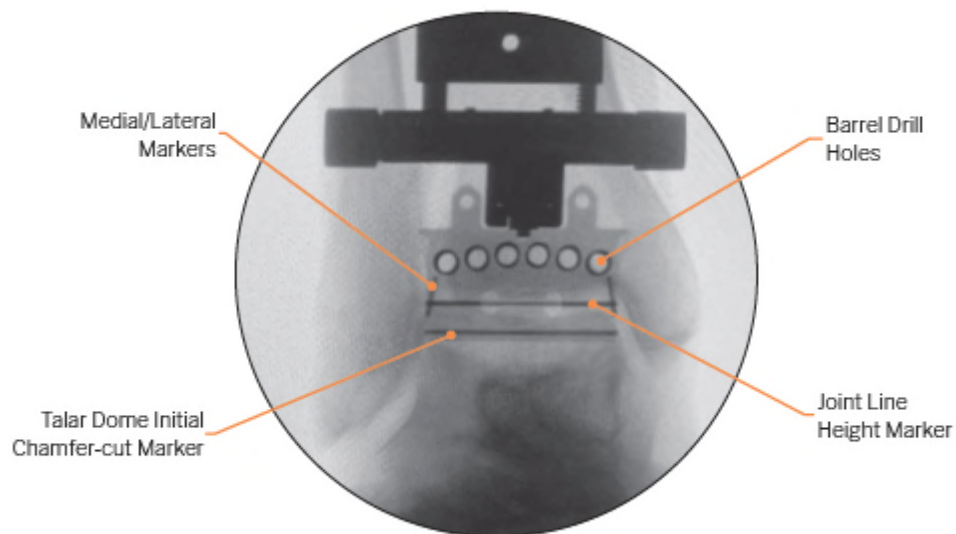
59. The APEX 3D System includes “a sizing pattern coupled to the body, the sizing pattern having a size and being coupled to the body at a location for estimating resectioning cuts to be made to the bone, wherein the sizing pattern comprises at least two radiopaque lines each

comprising a length dimension configured to provide a fluoroscopic cue for positioning the body,”
for example, as depicted and described in the APEX 3D System Surgical Technique Guides:

SIZING RESECTION BLOCK



(Ex. 3, APEX 3D System Surgical Technique Guide, at 7.)



(Ex. 3, APEX 3D System Surgical Technique Guide, at 8.)

SIZING EVALUATION

- Select and attach the appropriate Sizing Resection Block [P10-942-SZxx] based on pre-op planning, and estimated tibial sizing requirements.
- Under an AP Fluoroscopic view, evaluate initial position against M/L gutters, then swap blocks to adjust sizing as needed.

(Ex. 3, APEX 3D System Surgical Technique Guide, at 8.)

APEX 3D COLOR CODES					
Size 1 - Green	Size 2 - Yellow	Size 3 - Purple	Size 4 - Orange	Size 5 - Dark Blue	Size 6 - Bronze
					

(Ex. 3, APEX 3D System Surgical Technique Guide, at 8.)

VARUS / VALGUS ADJUSTMENTS

- With Sizing Block or optional JLR Angel Wing:
- Evaluate varus / valgus under an AP fluoroscopic view.
- To adjust varus / valgus alignment, rotate the Proximal Control Knobs.
- *(Optional)* Once confirmed, lock the gold screw adjacent to V/V proximal control knobs.

(Ex. 3, APEX 3D System Surgical Technique Guide, at 10.)

JOINT LINE HEIGHT: DISTAL - PROXIMAL MICRO ADJUSTMENTS

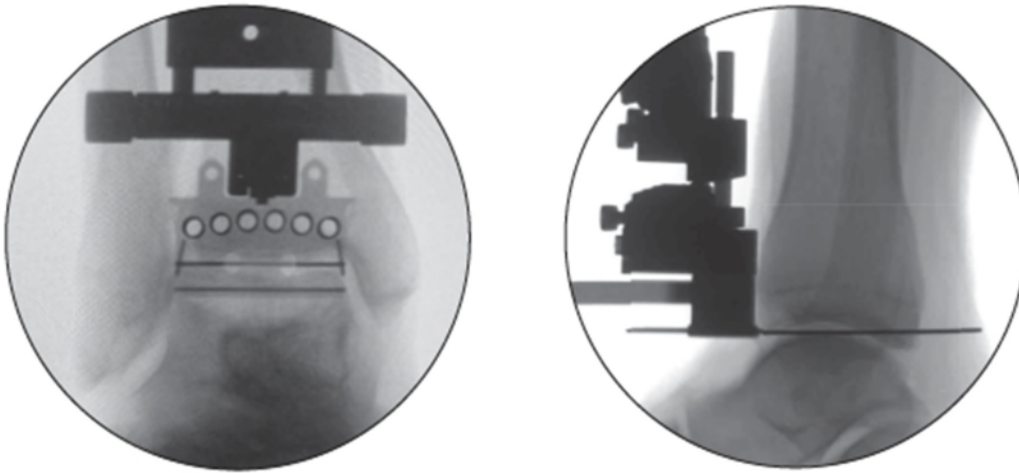
- Under an AP fluoroscopic view, evaluate and adjust joint line height by rotating the silver "UP/DOWN" control screw on the right side of the control block with hex driver.
- Once appropriate positioning has been determined, secure the joint line height by rotating the position locking gold screw.

(Ex. 3, APEX 3D System Surgical Technique Guide, at 11.)

MEDIAL - LATERAL MICRO ADJUSTMENTS

- Adjust medial / lateral (M/L) alignment by rotating the Distal Control Knobs.
- Use an AP fluoroscopic view to verify the Sizing Resection Block is aligned with the medial and lateral gutters.
- Lock in M/L alignment by rotating the center most gold screw until threads are fully seated.

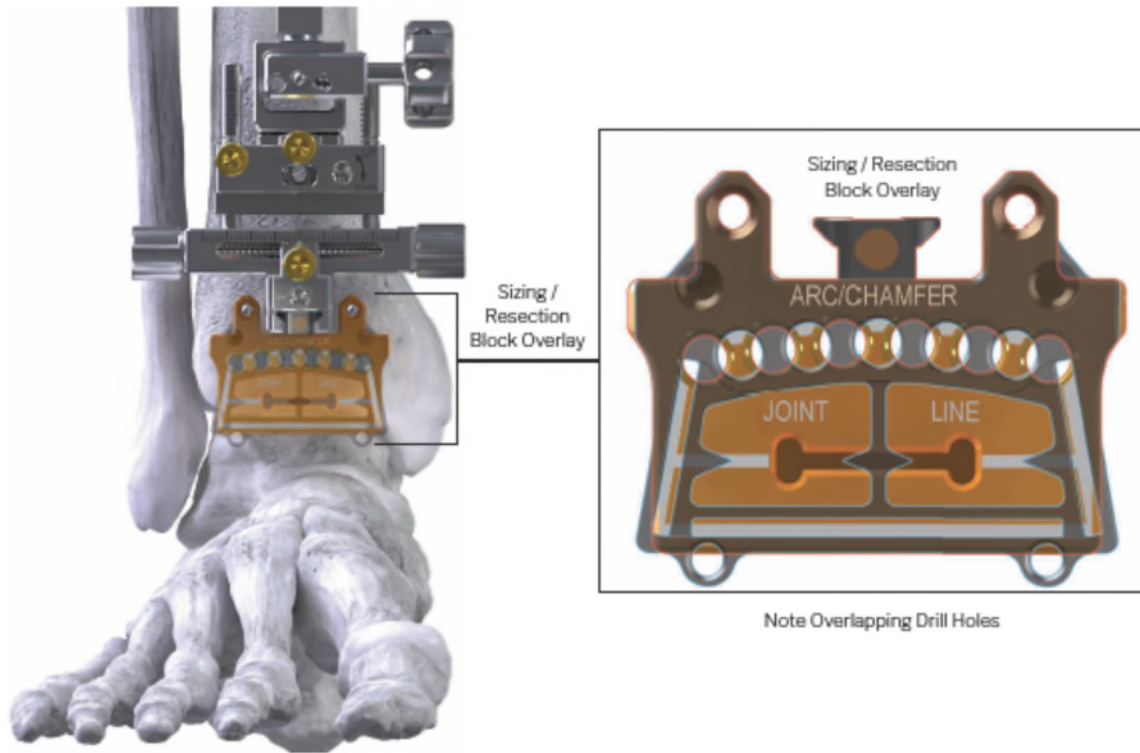
(Ex. 3, APEX 3D System Surgical Technique Guide, at 12.)



FINALIZE ALIGNMENT

- Confirm all planes of alignment visually and under fluoroscopy.
- Make final adjustments as necessary

(Ex. 3, APEX 3D System Surgical Technique Guide, at 13.)

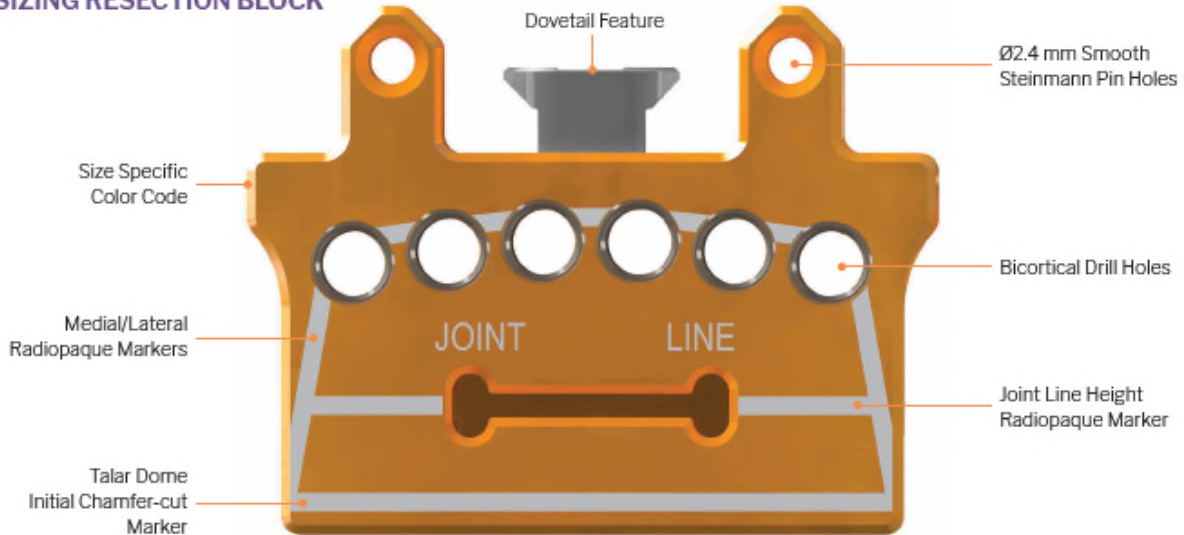


(Ex. 3, APEX 3D System Surgical Technique Guide, at 15; *see* Ex. 4, Maven Surgical Technique Guide, at 9; Ex. 5, FasTrac Surgical Technique Guide, at 8-11.)

60. Claim 2 of the 336 Patent recites: “[t]he surgical guide of claim 1, further comprising a plurality of pin holes sized and configured to receive a plurality of pins to couple the body to the bone.”

61. The APEX 3D System includes “[t]he surgical guide of claim 1” as explained above. The APEX 3D System also includes “a plurality of pin holes sized and configured to receive a plurality of pins to couple the body to the bone.” For example:

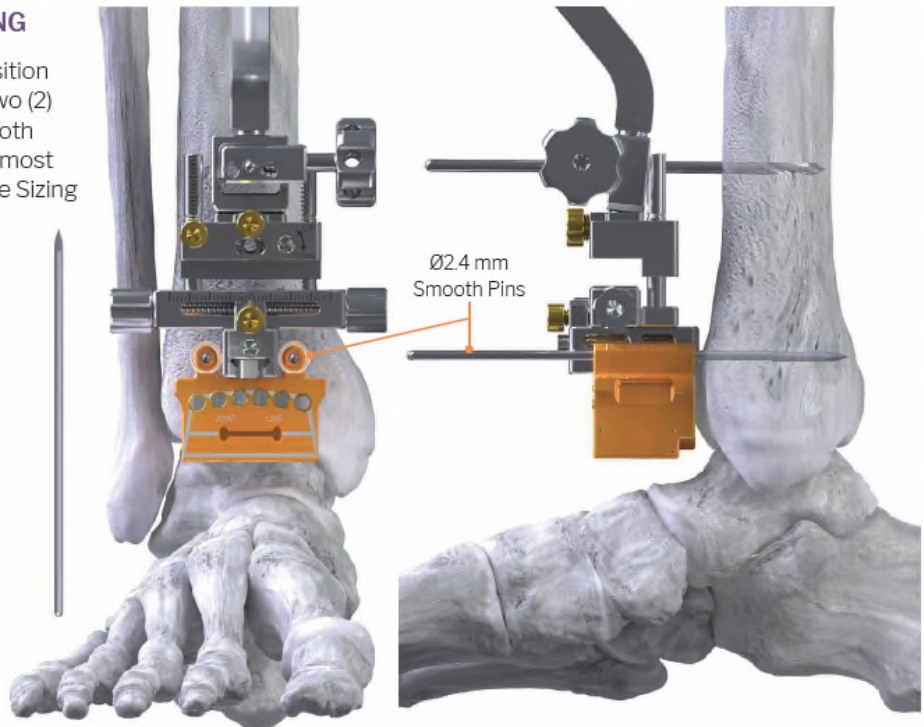
SIZING RESECTION BLOCK



(Ex. 3, APEX 3D System Surgical Technique Guide, at 8.)

LOCK FINAL POSITIONING

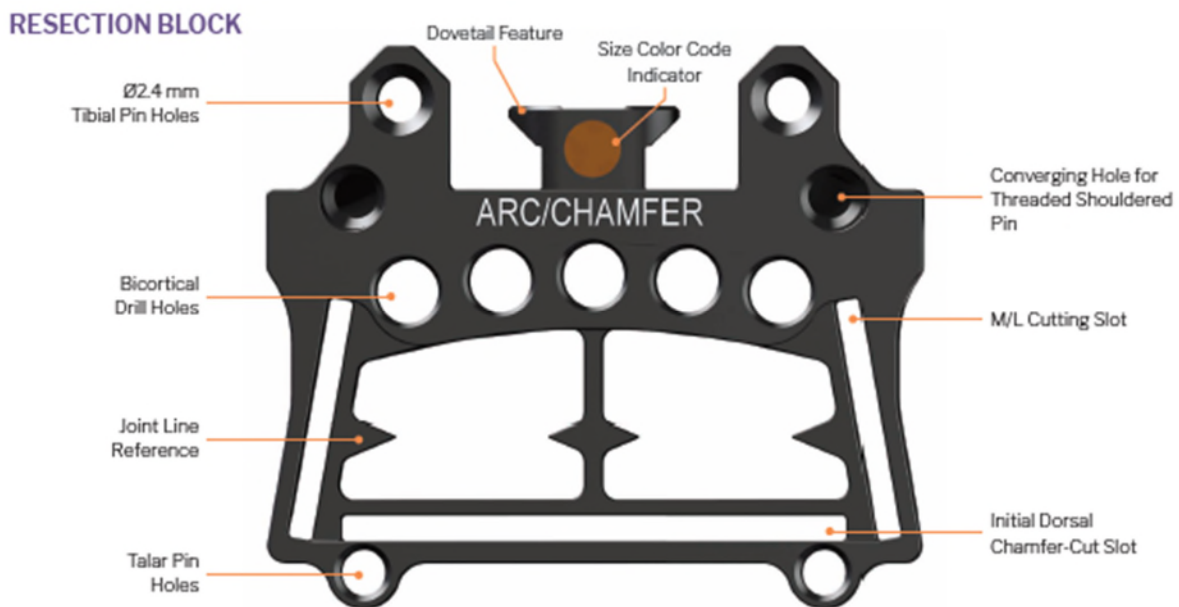
- To establish the final position against the tibia, place two (2) Ø2.4 mm x 110 mm Smooth Steinmann Pins into the most proximal M/L holes of the Sizing Resection Block.



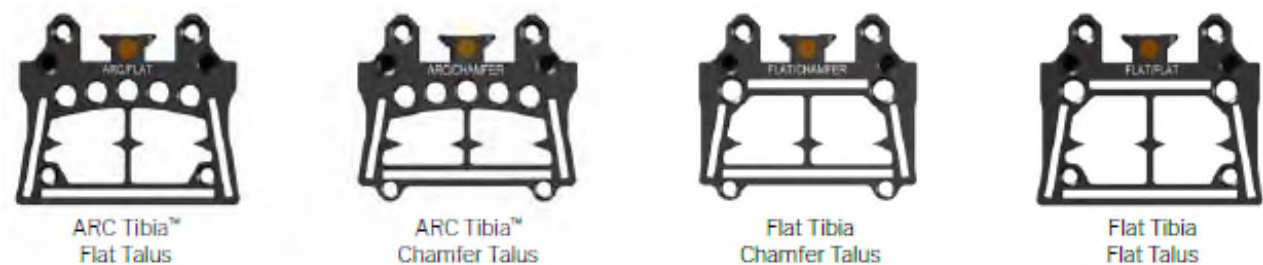
(Ex. 3, APEX 3D System Surgical Technique Guide, at 13; *see* Ex. 4, Maven Surgical Technique Guide, at 13; Ex. 5, FasTrac Surgical Technique Guide, at 11.)

62. Claim 3 of the 336 Patent recites: “[t]he surgical guide of claim 1, further comprising a cut guide comprising a plurality of slots configured to position a cutting tool to cut the bone, wherein the size of the slots correspond to the sizing pattern.”

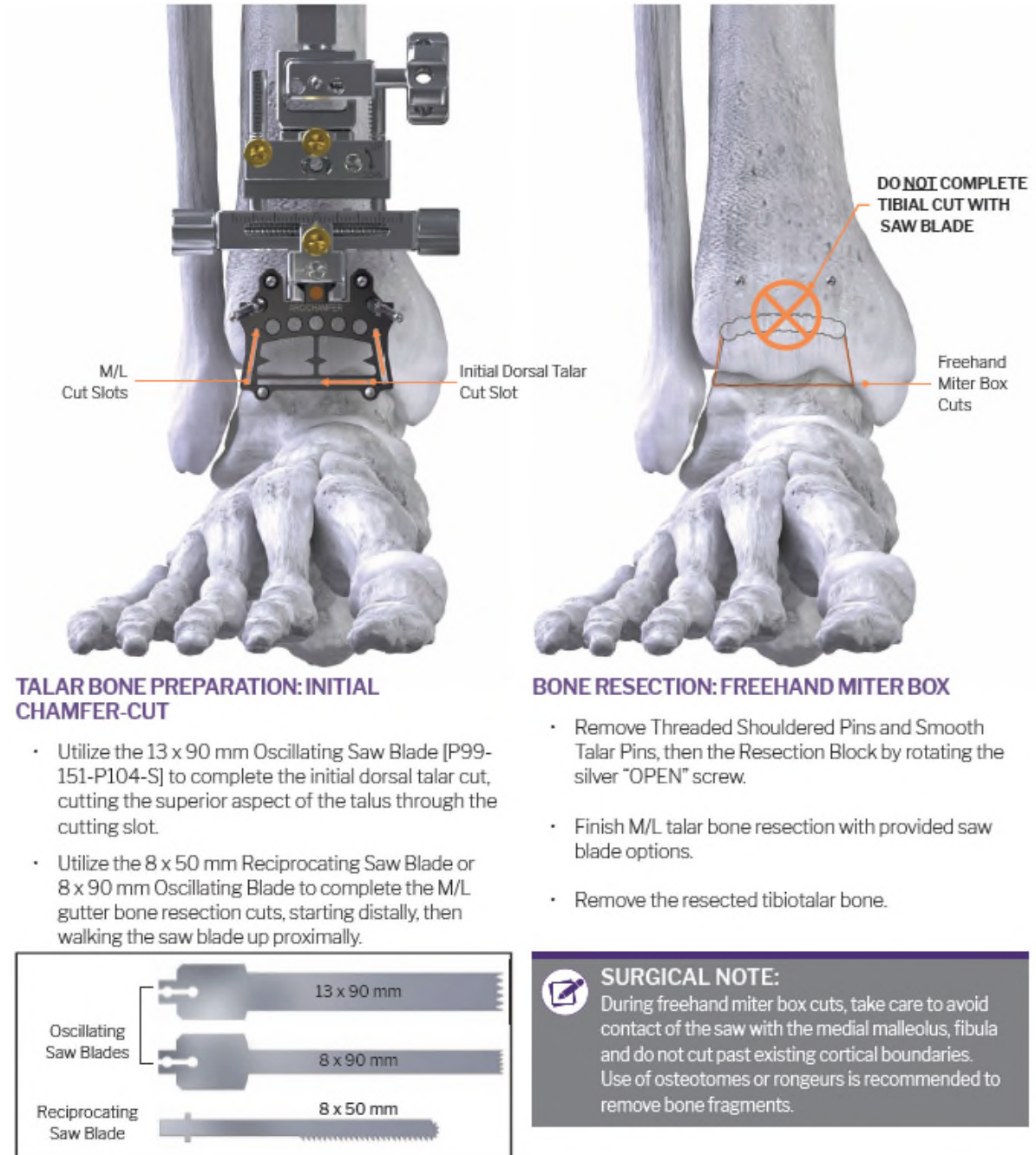
63. The APEX 3D System includes “[t]he surgical guide of claim 1” as explained above. The APEX 3D System further comprises “a cut guide comprising a plurality of slots configured to position a cutting tool to cut the bone, wherein the size of the slots correspond to the sizing pattern.” For example:



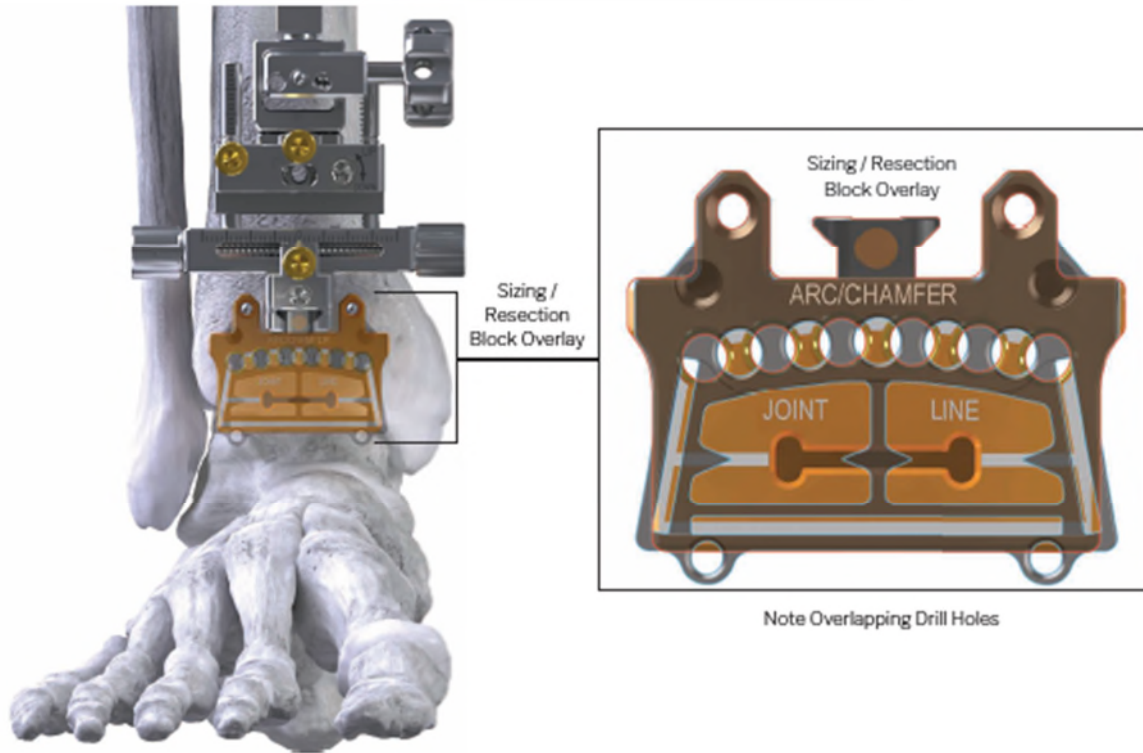
(Ex. 3, APEX 3D System Surgical Technique Guide, at 15.)



(Ex. 3, APEX 3D Total Ankle Replacement System Brochure, at 4.)



(Ex. 3, APEX 3D System Surgical Technique Guide, at 18.)

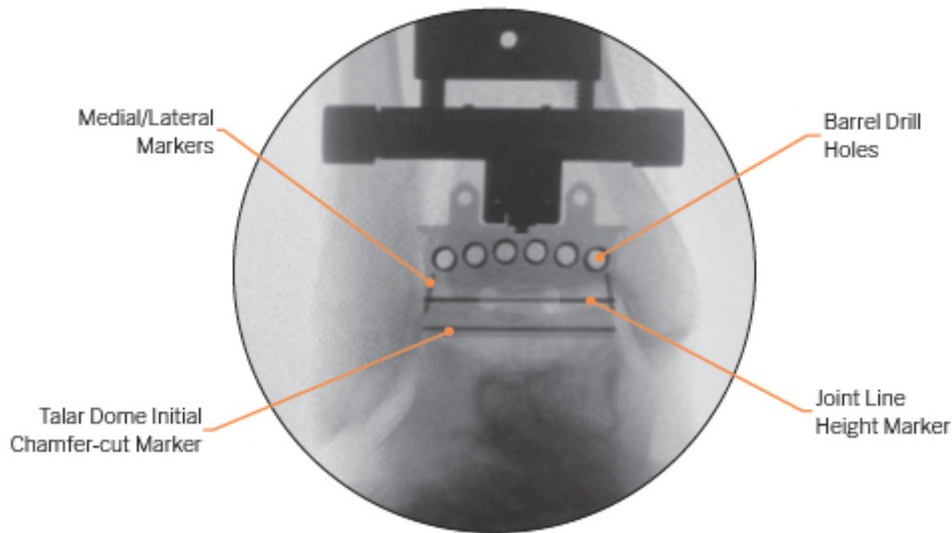
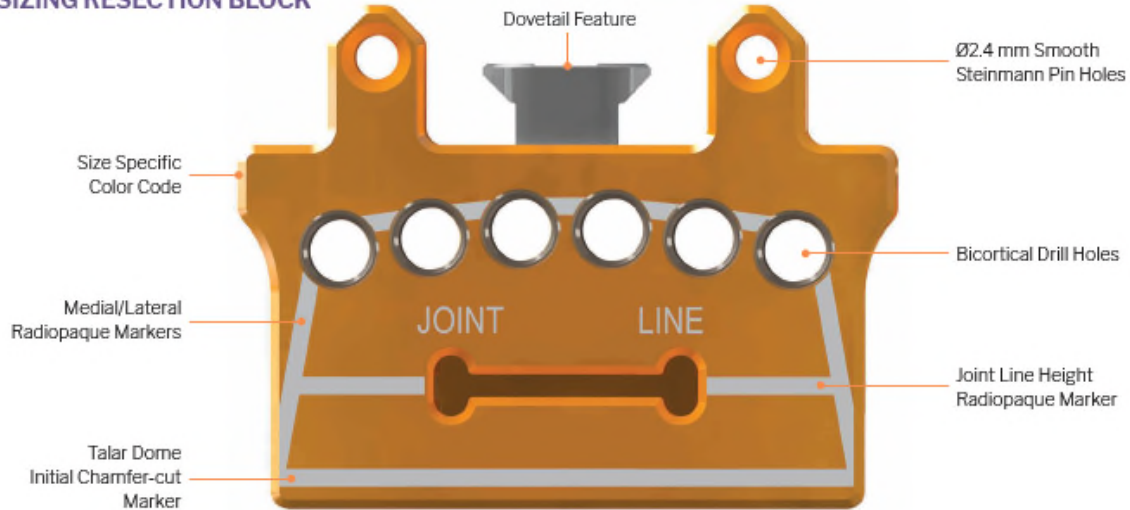


(Ex. 3, APEX 3D System Surgical Technique Guide, at 15; *see* Ex. 4, Maven Surgical Technique Guide, at 9; Ex. 5, FasTrac Surgical Technique Guide, at 8-11.)

64. Claim 4 of the 336 Patent recites: “[t]he surgical guide of claim 1, wherein the body comprises a plastic material and the first guide hole, the second guide hole, and the sizing pattern comprise a metal material.”

65. The APEX 3D System includes “[t]he surgical guide of claim 1” as explained above. The APEX 3D System also includes “wherein the body comprises a plastic material and the first guide hole, the second guide hole, and the sizing pattern comprise a metal material,” for example, as can be seen from the APEX 3D System Surgical Technique Guides:

SIZING RESECTION BLOCK

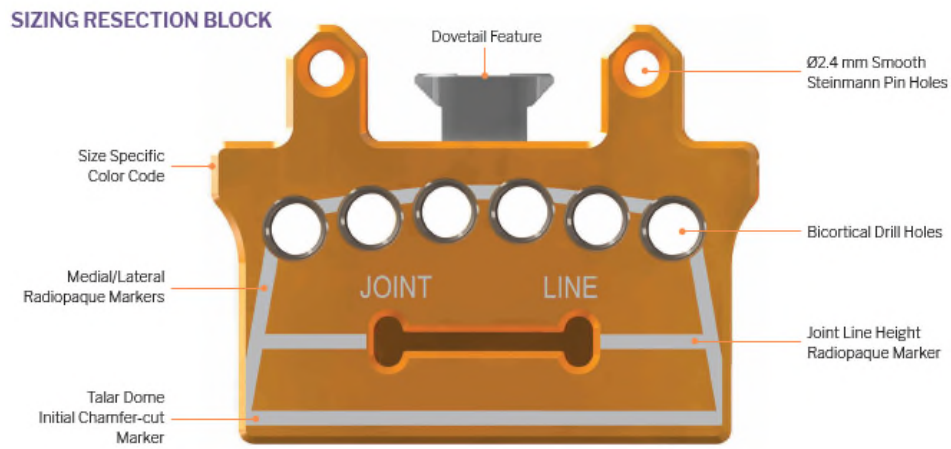


(Ex. 3, APEX 3D System Surgical Technique Guide, at 8.)

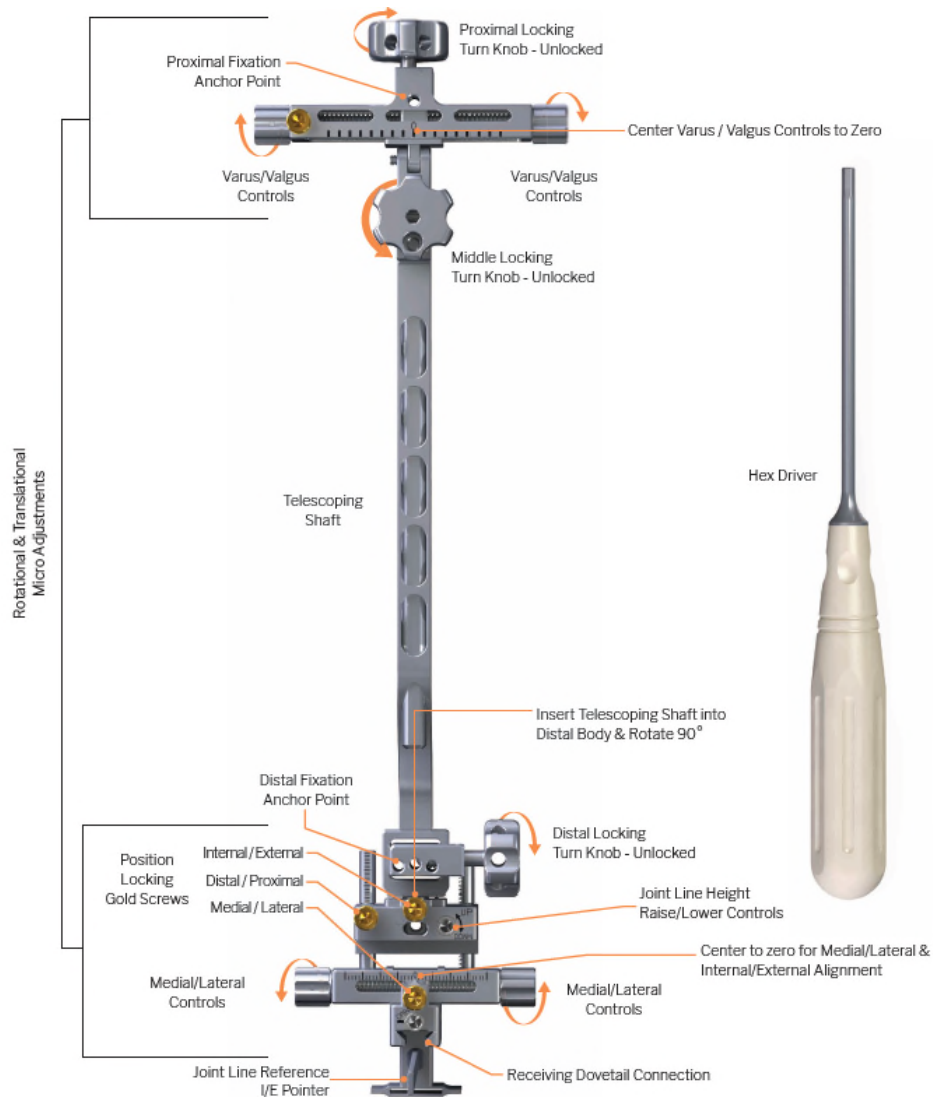
66. Claim 5 of the 336 Patent recites: “[t]he surgical guide of claim 1, wherein the body comprises a dovetail extension configured to be coupled to a dovetail joint of the block.”

67. The APEX 3D System includes “[t]he surgical guide of claim 1” as explained above. The APEX 3D System includes “wherein the body comprises a dovetail extension

configured to be coupled to a dovetail joint of the block,” for example, as described and depicted in the Surgical Technique Guides for the APEX 3D System:

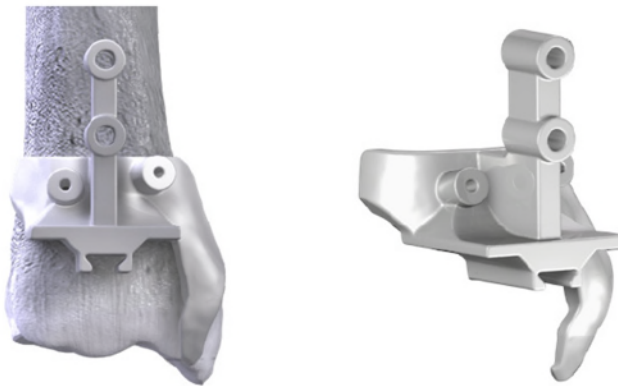


(Ex. 3, APEX 3D System Surgical Technique Guide, at 8.)

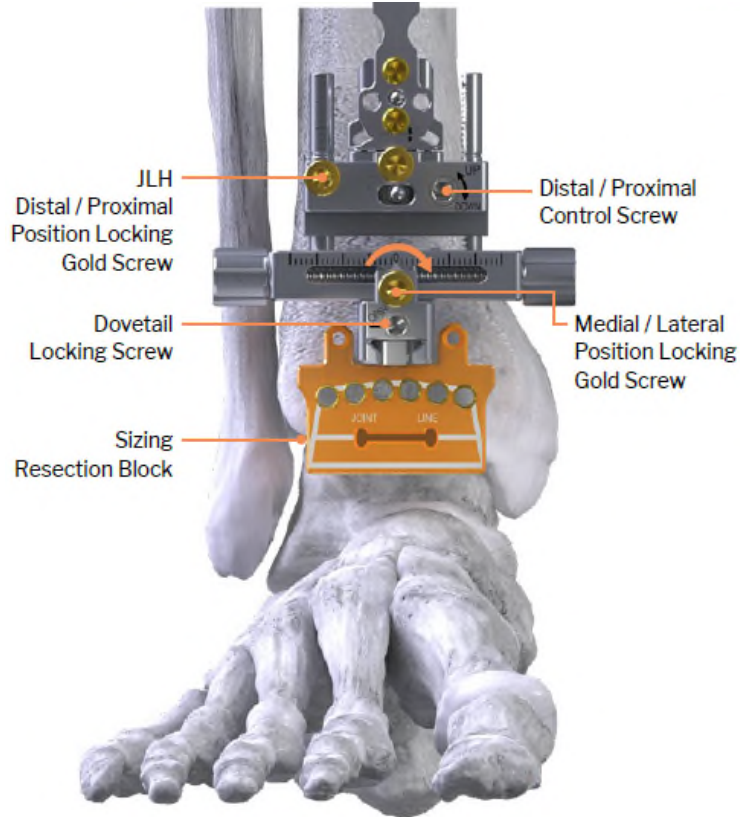


(Ex. 3, APEX 3D System Surgical Technique Guide, at 4.)

Tibia PSI Guide & Bone Model



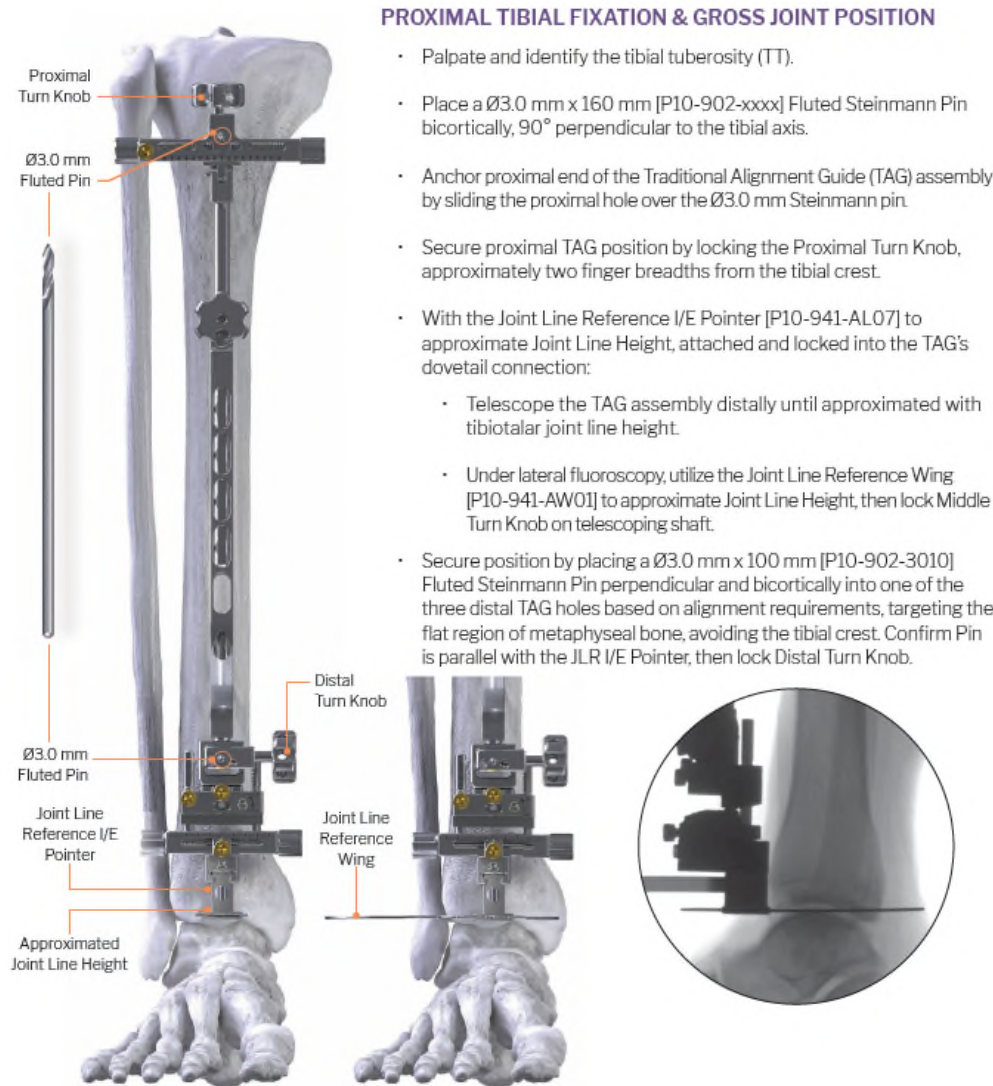
(Ex. 4, Maven Surgical Technique Guide, at 3.)



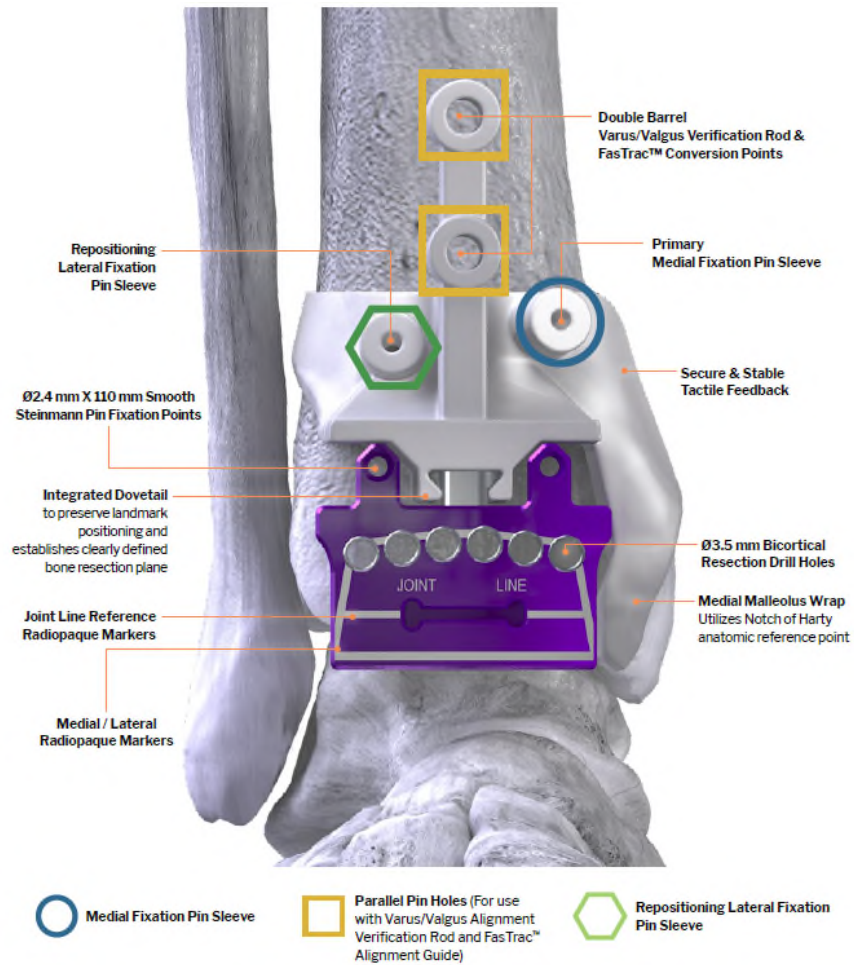
(Ex. 5, FasTrac Surgical Technique Guide, at 10.)

68. Claim 6 of the 336 Patent recites: “[t]he surgical guide of claim 1, wherein the body comprises a plurality of pin holes configured to receive a plurality of pins to couple the body to at least the tibia.”

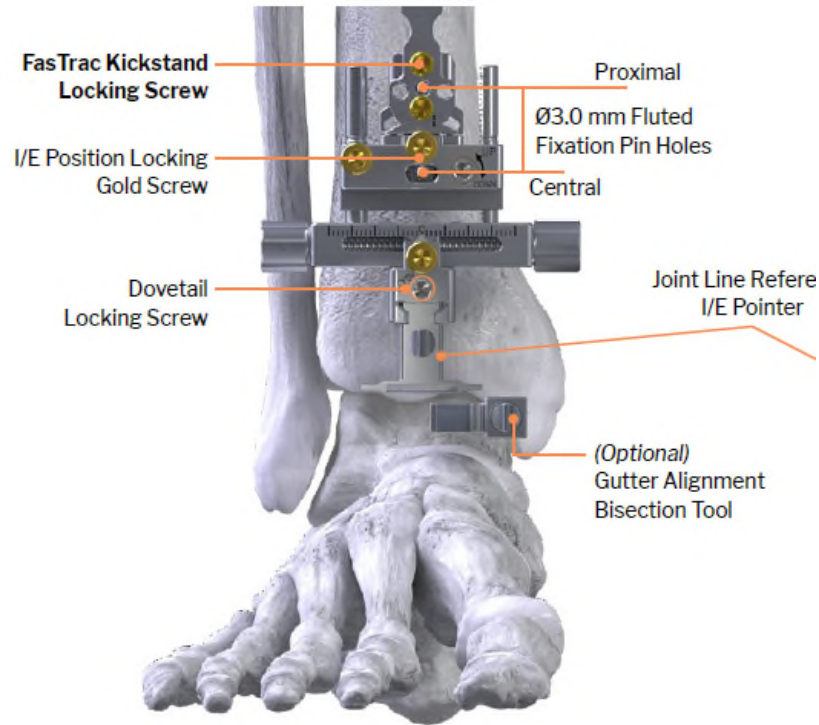
69. The APEX 3D System includes “[t]he surgical guide of claim 1” as explained above. The APEX 3D System also includes “wherein the body comprises a plurality of pin holes configured to receive a plurality of pins to couple the body to at least the tibia,” as depicted in the in the Surgical Technique Guides for the APEX 3D System, for example:



(Ex. 3, APEX 3D System Surgical Technique Guide, at 5.)



(Ex. 4, Maven Surgical Technique Guide, at 7.)

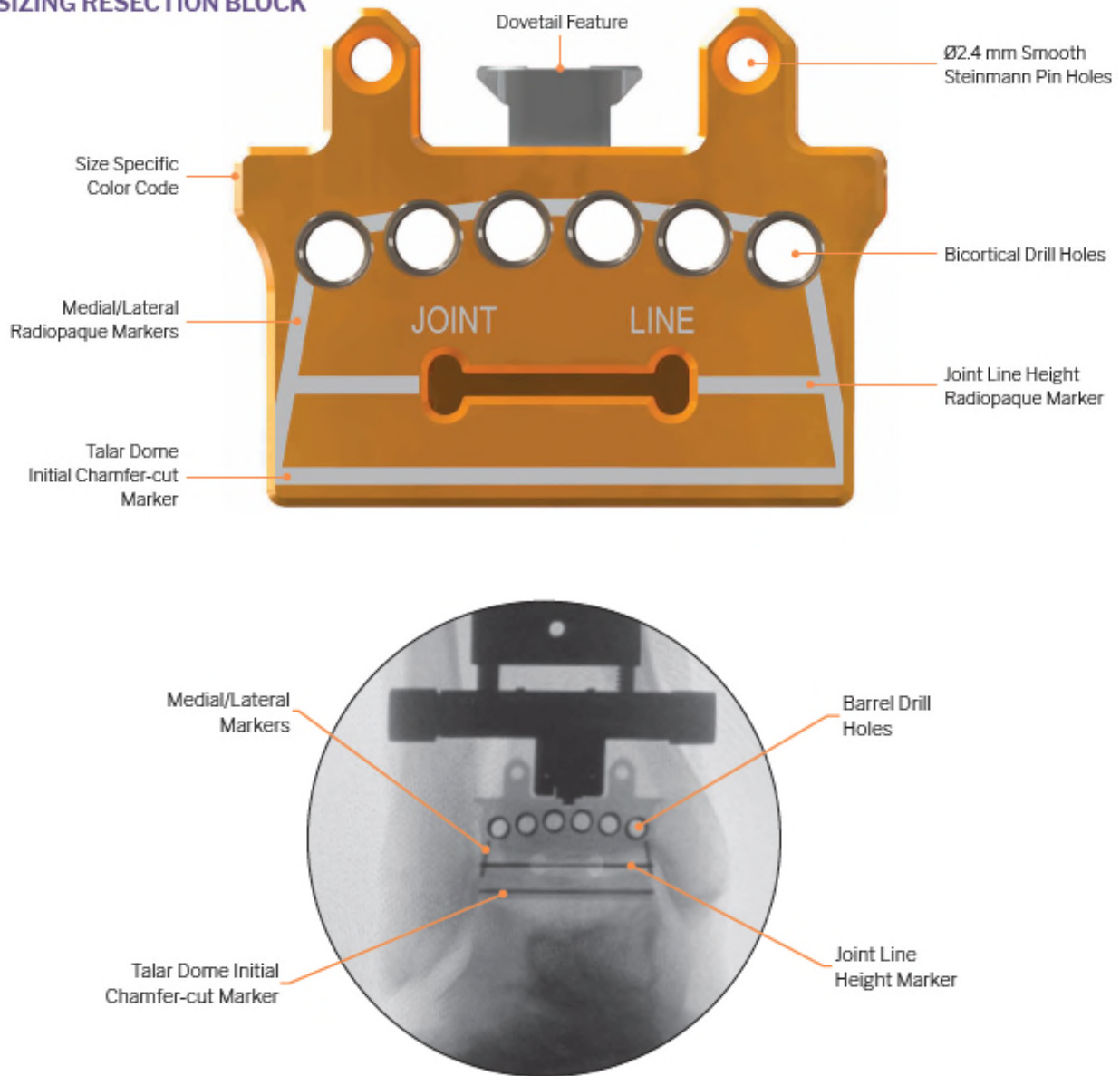


(Ex. 5, FasTrac Surgical Technique Guide, at 7-8.)

70. Claim 8 of the 336 Patent recites: “[t]he surgical guide of claim 1, wherein the at least two radiopaque lines comprise at least two parallel radiopaque lines.”

71. The APEX 3D System includes “[t]he surgical guide of claim 1” as explained above. The APEX 3D System also includes “wherein the at least two radiopaque lines comprise at least two parallel radiopaque lines,” as shown below in the Surgical Technique Guides for the APEX 3D System, for example:

SIZING RESECTION BLOCK

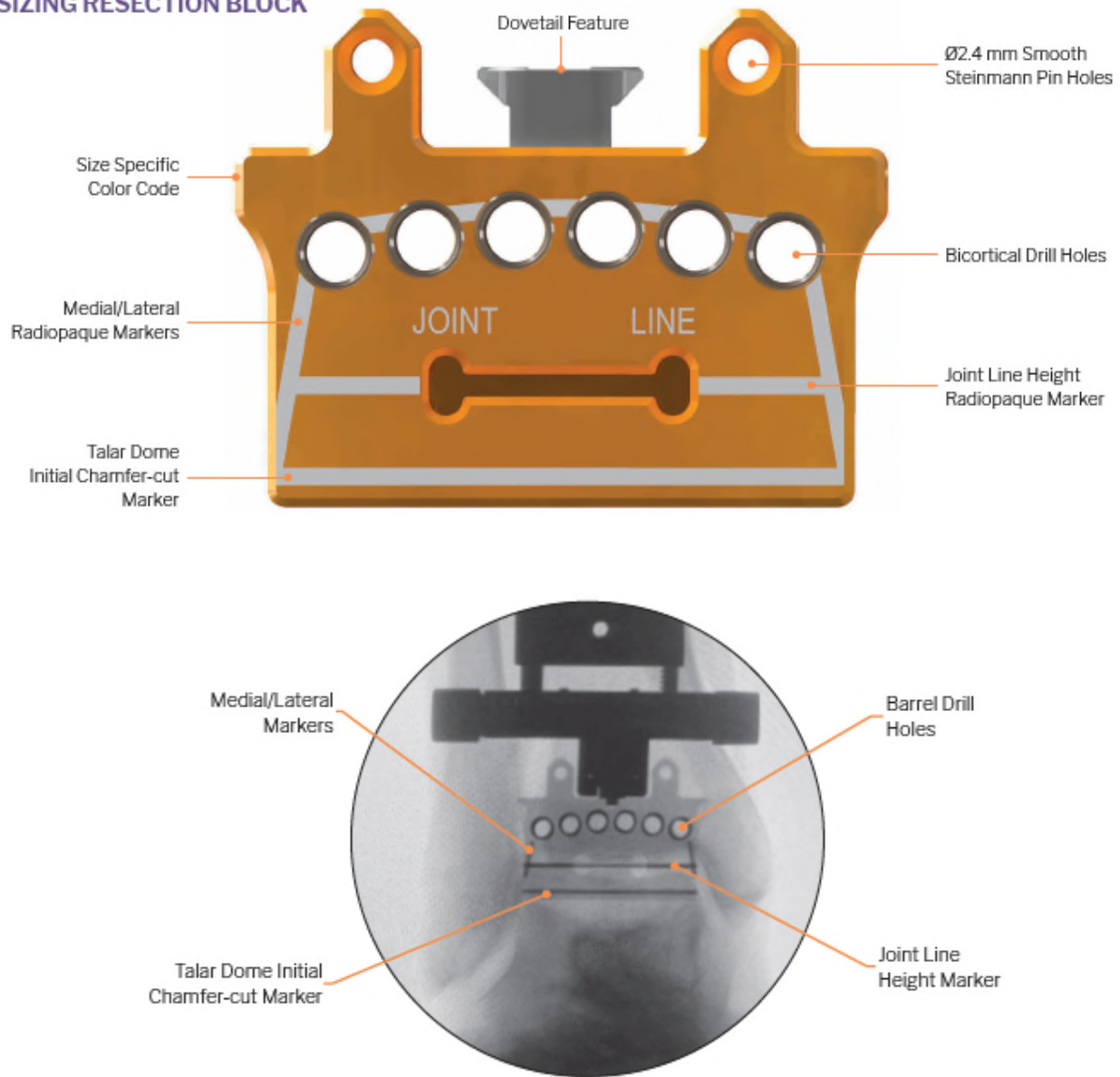


(Ex. 3, APEX 3D System Surgical Technique Guide, at 8.)

72. Claim 9 of the 336 Patent recites: “[t]he surgical guide of claim 1, wherein the at least two radiopaque lines comprise a first line extending generally in a medial-lateral direction, a second line extending generally in a proximal-distal direction, and a third line extending generally in a proximal-distal direction.”

73. The APEX 3D System includes “[t]he surgical guide of claim 1” as explained above. The APEX 3D System also includes “wherein the at least two radiopaque lines comprise a first line extending generally in a medial-lateral direction, a second line extending generally in a proximal-distal direction, and a third line extending generally in a proximal-distal direction,” for example, as depicted in the Surgical Technique Guides for the APEX 3D System:

SIZING RESECTION BLOCK



(Ex. 3, APEX 3D System Surgical Technique Guide, at 8.)

74. Claim 10 of the 336 Patent recites:

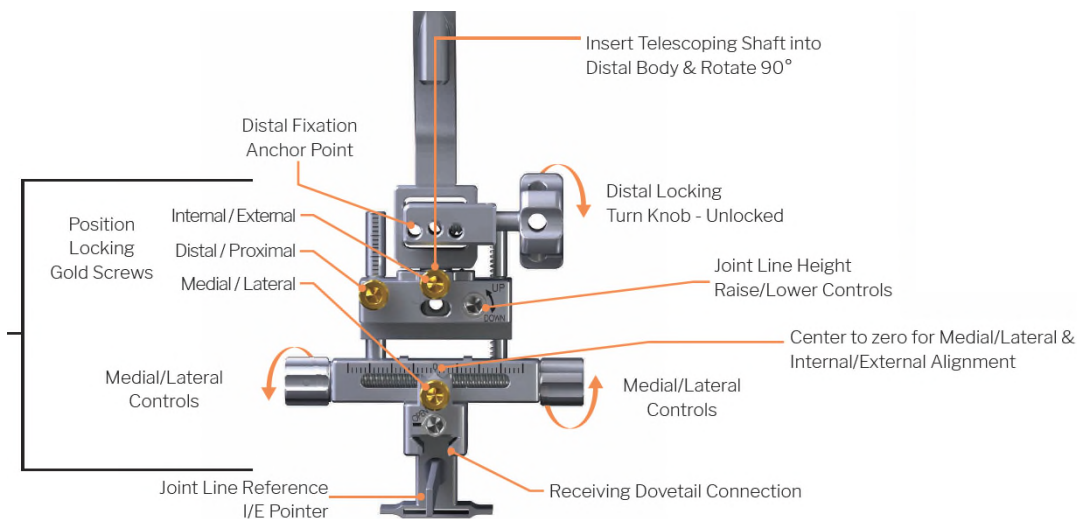
An adjustable guide assembly comprising:

one or more positionable frames configured to provide at least proximal-distal and medial-lateral adjustments; and

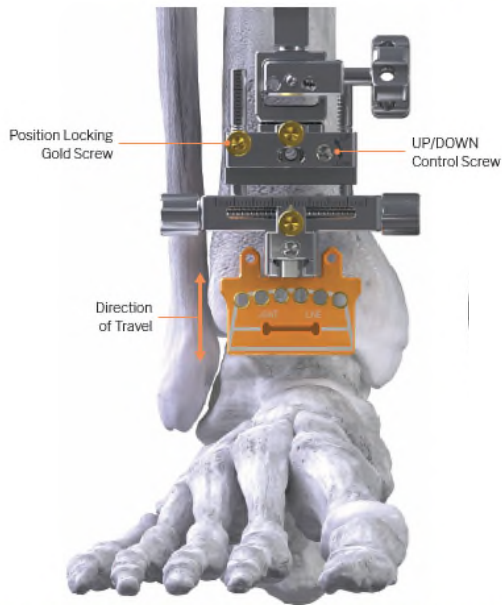
a guide coupled to the one or more positionable frames such that adjustment of at least one of the one or more positionable frames changes the position of the guide,

wherein the guide comprises a plurality of radiopaque surfaces defining a plurality of drill holes in a surface of the guide and at least one radiopaque line on the surface of the guide comprising a length dimension configured to provide a fluoroscopic cue for positioning the guide by the one or more positionable frames.

75. The APEX 3D System includes “[a]n adjustable guide assembly comprising: one or more positionable frames configured to provide at least proximal-distal and medial-lateral adjustments.” For example, the APEX 3D System meets the limitation, as depicted below for the APEX 3D System Traditional Alignment Guide and FasTrac:

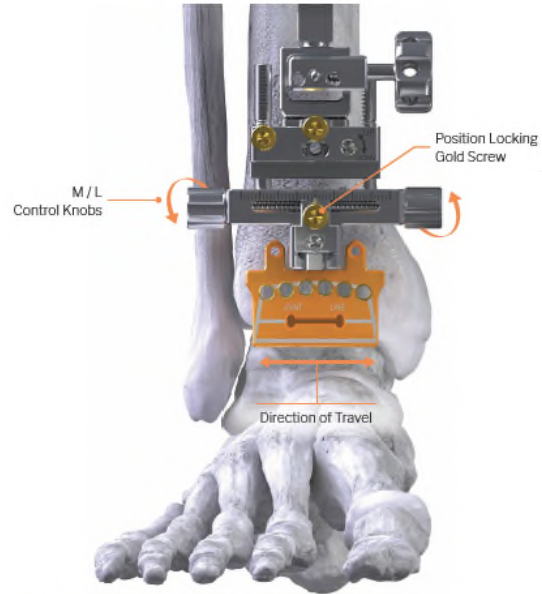


(Ex. 3, APEX 3D System Surgical Technique Guide, at 4.)



JOINT LINE HEIGHT: DISTAL - PROXIMAL MICRO ADJUSTMENTS

- Under an AP fluoroscopic view, evaluate and adjust joint line height by rotating the silver "UP/DOWN" control screw on the right side of the control block with hex driver.
- Once appropriate positioning has been determined, secure the joint line height by rotating the position locking gold screw.

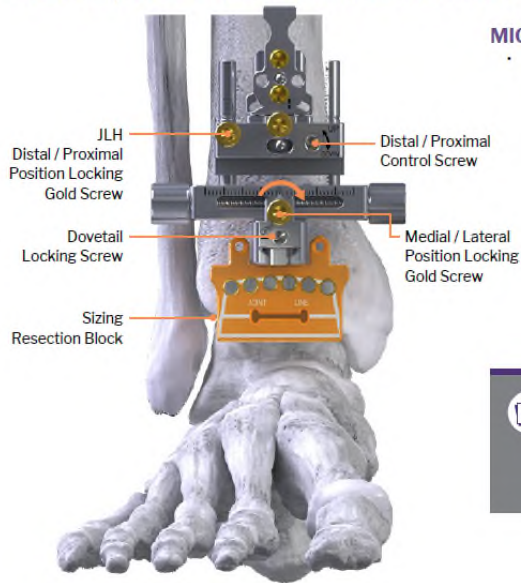


MEDIAL - LATERAL MICRO ADJUSTMENTS

- Adjust medial / lateral (M/L) alignment by rotating the Distal Control Knobs.
- Use an AP fluoroscopic view to verify the Sizing Resection Block is aligned with the medial and lateral gutters.
- Lock in M/L alignment by rotating the center most gold screw until threads are fully seated.

(Ex. 3, APEX 3D System Surgical Technique Guide, at 11-12.)

FasTrac™ MICRO ADJUSTMENTS – SIZING, MEDIAL/LATERAL & JOINT LINE HEIGHT



MICRO ADJUSTMENTS

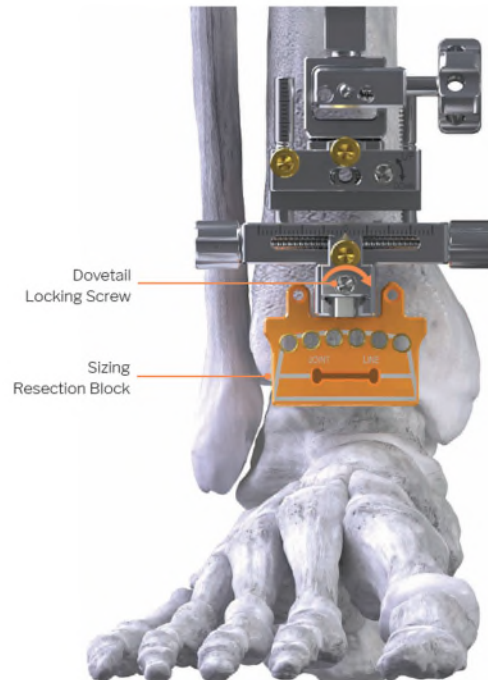
- Under an AP fluoroscopic view, evaluate and adjust:
 - Sizing, then swap blocks to adjust as necessary, then lock the associated silver dovetail screw.
 - Medial/Lateral alignment, then secure position by locking the associated gold screw.
 - Joint line height against interoperative anatomic landmarks, then secure position by locking the associated gold screw.



SURGICAL NOTE:

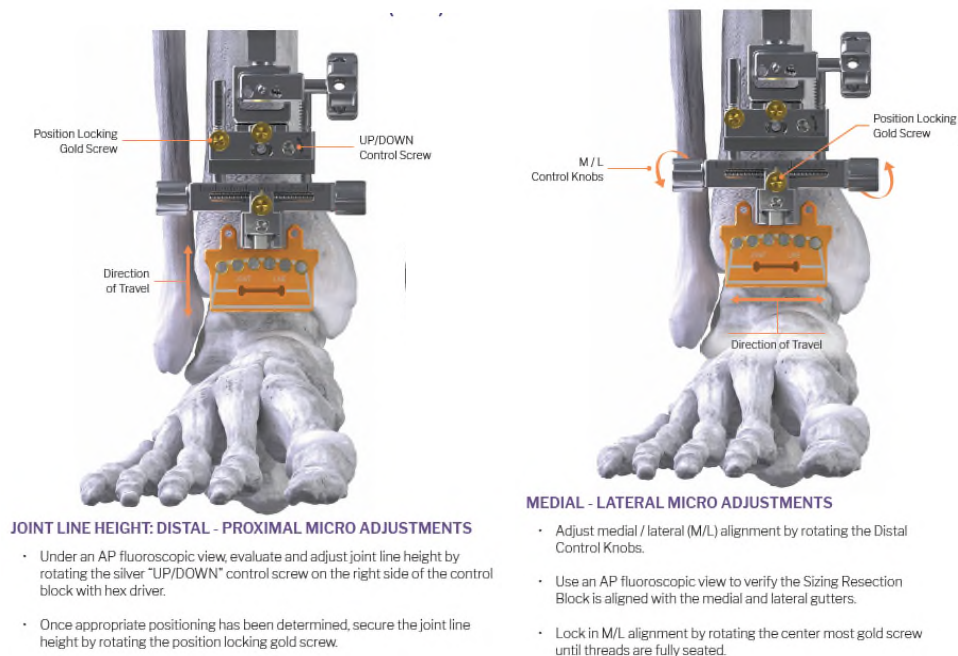
Radiopaque alignment markers within the Sizing Resection Block are used to evaluate appropriate size, joint line positioning and medial / lateral position within tibiotalar joint.

(Ex. 5, FasTrac Surgical Technique Guide, at 10.)



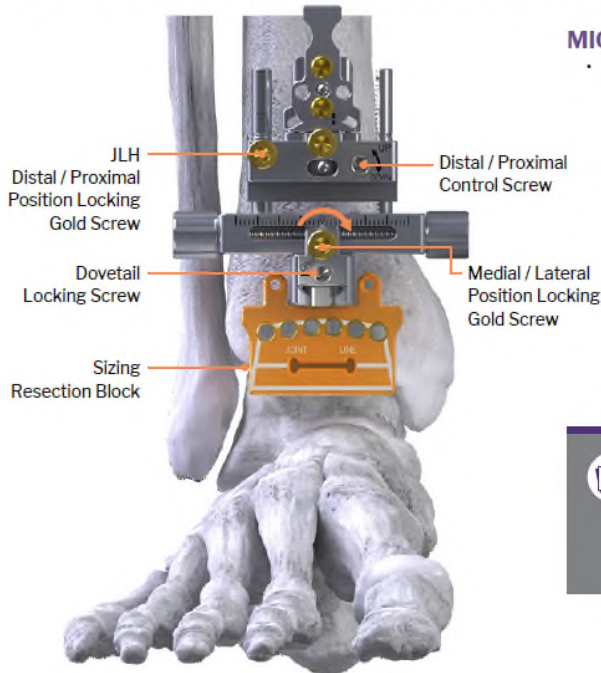
(Ex. 3, APEX 3D System Surgical Technique Guide, at 9.)

76. The APEX 3D System includes “a guide coupled to the one or more positionable frames such that adjustment of at least one of the one or more positionable frames changes the position of the guide.” For example:



(Ex. 3, APEX 3D System Surgical Technique Guide, at 9, 11-12.)

FasTrac™ MICRO ADJUSTMENTS – SIZING, MEDIAL/LATERAL & JOINT LINE HEIGHT



MICRO ADJUSTMENTS

- Under an AP fluoroscopic view, evaluate and adjust:
 - Sizing, then swap blocks to adjust as necessary, then lock the associated silver dovetail screw.
 - Medial/Lateral alignment, then secure position by locking the associated gold screw.
 - Joint line height against interoperative anatomic landmarks, then secure position by locking the associated gold screw.

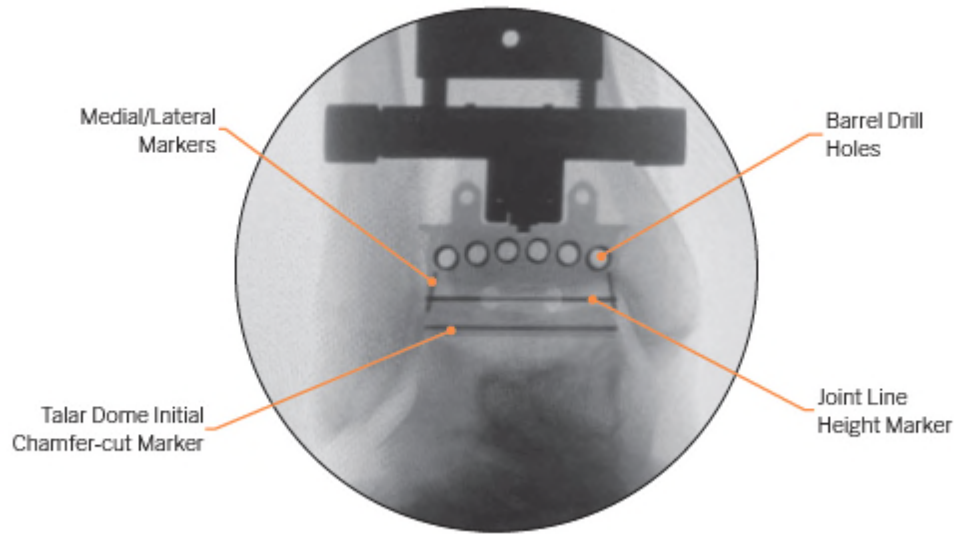


SURGICAL NOTE:

Radiopaque alignment markers within the Sizing Resection Block are used to evaluate appropriate size, joint line positioning and medial / lateral position within tibiotalar joint.

(Ex. 5, FasTrac Surgical Technique Guide, at 9.)

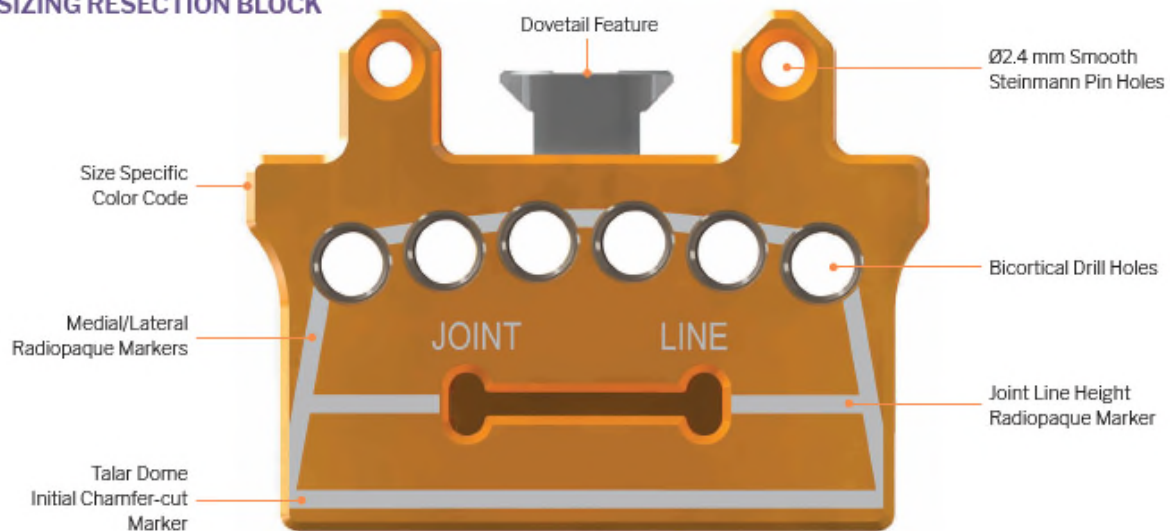
77. The APEX 3D System includes “wherein the guide comprises a plurality of radiopaque surfaces defining a plurality of drill holes in a surface of the guide.” For example:



(Ex. 3, APEX 3D System Surgical Technique Guide, at 8.)

TRADITIONAL ALIGNMENT GUIDE (TAG)

SIZING RESECTION BLOCK



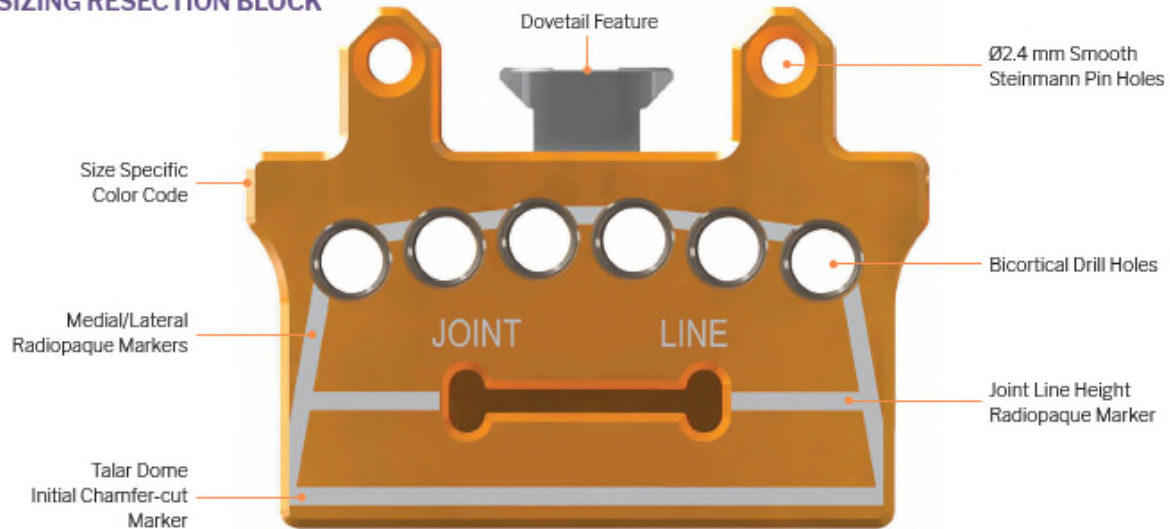
(Ex. 3, APEX 3D System Surgical Technique Guide, at 8; *see* Ex. 4, Maven Surgical Technique Guide, at 7; Ex. 5, FasTrac Surgical Technique Guide, at 4.)

78. The APEX 3D System includes “at least one radiopaque line on the surface of the guide comprising a length dimension configured to provide a fluoroscopic cue for positioning the

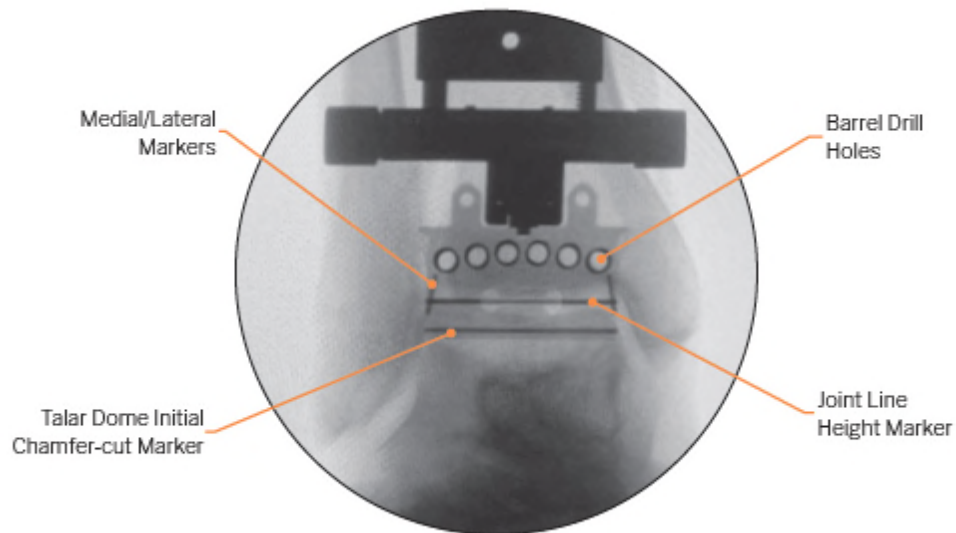
guide by the one or more positionable frames.” For example, as depicted and instructed by the Surgical Technique Guides for the APEX 3D System:

TRADITIONAL ALIGNMENT GUIDE (TAG)

SIZING RESECTION BLOCK



(Ex. 3, APEX 3D System Surgical Technique Guide, at 7.)



(Ex. 3, APEX 3D System Surgical Technique Guide, at 8.)

SIZING EVALUATION

- Select and attach the appropriate Sizing Resection Block [P10-942-SZxx] based on pre-op planning, and estimated tibial sizing requirements.
- Under an AP Fluoroscopic view, evaluate initial position against M/L gutters, then swap blocks to adjust sizing as needed.

(Ex. 3, APEX 3D System Surgical Technique Guide, at 9.)

VARUS / VALGUS ADJUSTMENTS

- With Sizing Block or optional JLR Angel Wing:
- Evaluate varus / valgus under an AP fluoroscopic view.
- To adjust varus / valgus alignment, rotate the Proximal Control Knobs.
- *(Optional)* Once confirmed, lock the gold screw adjacent to V/V proximal control knobs.

(Ex. 3, APEX 3D System Surgical Technique Guide, at 10.)

JOINT LINE HEIGHT: DISTAL - PROXIMAL MICRO ADJUSTMENTS

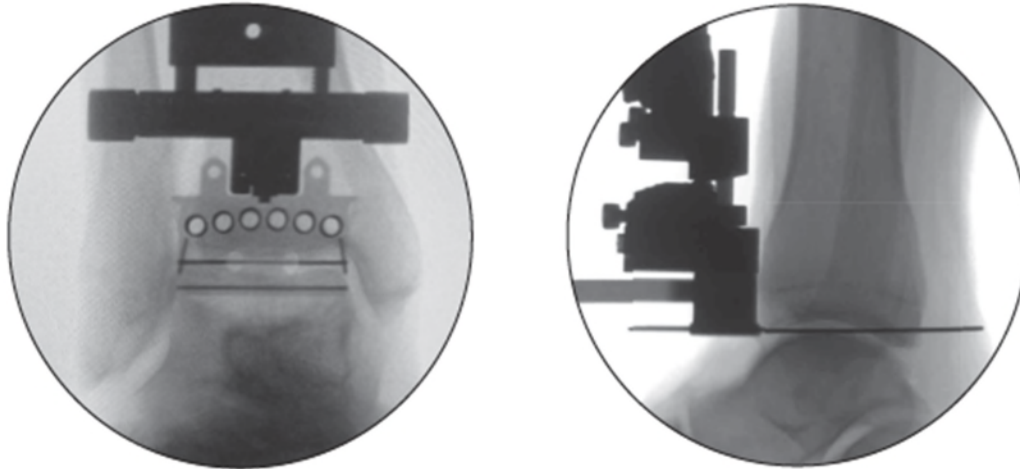
- Under an AP fluoroscopic view, evaluate and adjust joint line height by rotating the silver "UP/DOWN" control screw on the right side of the control block with hex driver.
- Once appropriate positioning has been determined, secure the joint line height by rotating the position locking gold screw.

(Ex. 3, APEX 3D System Surgical Technique Guide, at 11.)

MEDIAL - LATERAL MICRO ADJUSTMENTS

- Adjust medial / lateral (M/L) alignment by rotating the Distal Control Knobs.
- Use an AP fluoroscopic view to verify the Sizing Resection Block is aligned with the medial and lateral gutters.
- Lock in M/L alignment by rotating the center most gold screw until threads are fully seated.

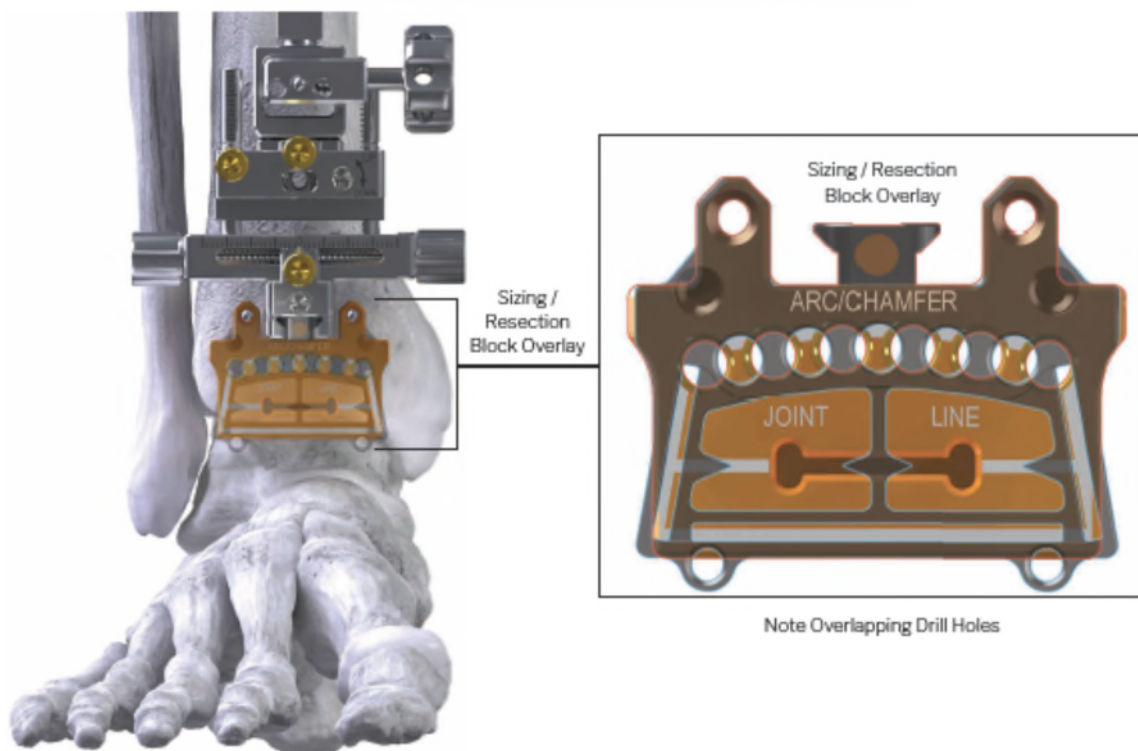
(Ex. 3, APEX 3D System Surgical Technique Guide, at 12.)



FINALIZE ALIGNMENT

- Confirm all planes of alignment visually and under fluoroscopy.
- Make final adjustments as necessary

(Ex. 3, APEX 3D System Surgical Technique Guide, at 13.)



(Ex. 3, APEX 3D System Surgical Technique Guide, at 15; *see* Ex. 4, Maven Surgical Technique Guide, at 9; Ex. 5, FasTrac Surgical Technique Guide, at 8-11.)

79. Claim 11 of the 336 Patent recites:

An adjustable guide assembly comprising:

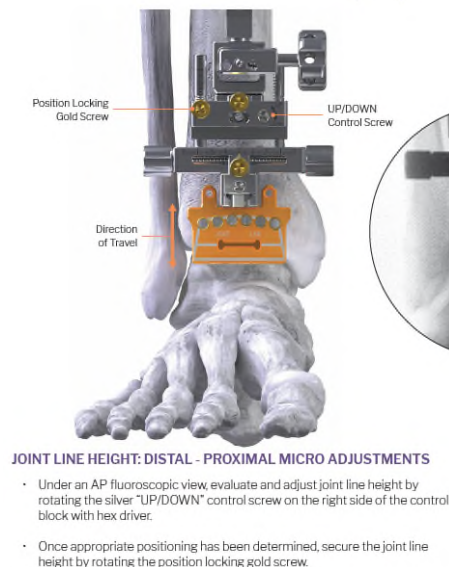
two independently positionable frames suitable for locating a tool relative to a joint of a patient, the frames comprising:

a first frame releasably secured to at least one fixation pin configured to project outwardly from an anterior surface of a bone located adjacent to the joint, the first frame being coupled to a first threaded shaft so that upon turning the first threaded shaft, the first frame is movable to effect a proximal-distal position adjustment of the tool; and

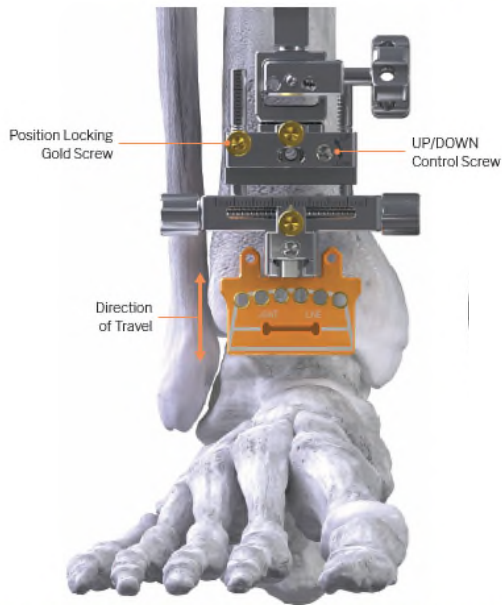
a second frame secured to the first frame, the second frame being coupled to a second threaded shaft so that upon turning the second threaded shaft, the second frame is movable to effect a medial-lateral adjustment of the tool; and

a guide coupled to each of the frames so as to be located adjacent to the joint and positionable relative to the bone with reference to a radiopaque line located on the guide.

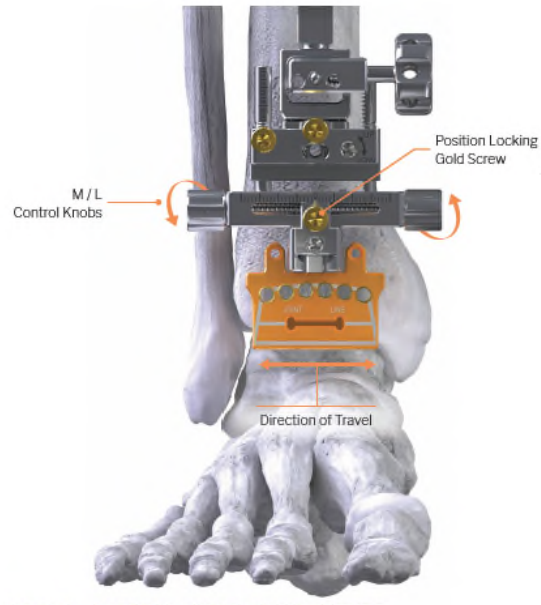
80. The APEX 3D System includes “[a]n adjustable guide assembly comprising: two independently positionable frames suitable for locating a tool relative to a joint of a patient,” for example, as depicted and described below for the APEX 3D System, including the Traditional Alignment Guide and a FasTrac:



(Ex. 3, APEX 3D System Surgical Technique Guide, at 4.)

**JOINT LINE HEIGHT: DISTAL - PROXIMAL MICRO ADJUSTMENTS**

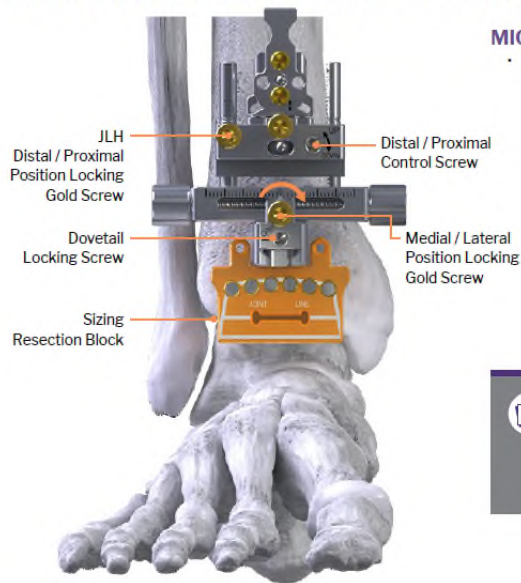
- Under an AP fluoroscopic view, evaluate and adjust joint line height by rotating the silver "UP/DOWN" control screw on the right side of the control block with hex driver.
- Once appropriate positioning has been determined, secure the joint line height by rotating the position locking gold screw.

**MEDIAL - LATERAL MICRO ADJUSTMENTS**

- Adjust medial / lateral (M/L) alignment by rotating the Distal Control Knobs.
- Use an AP fluoroscopic view to verify the Sizing Resection Block is aligned with the medial and lateral gutters.
- Lock in M/L alignment by rotating the center most gold screw until threads are fully seated.

(Ex. 3, APEX 3D System Surgical Technique Guide, at 11-12.)

FasTrac™ MICRO ADJUSTMENTS – SIZING, MEDIAL/LATERAL & JOINT LINE HEIGHT

**MICRO ADJUSTMENTS**

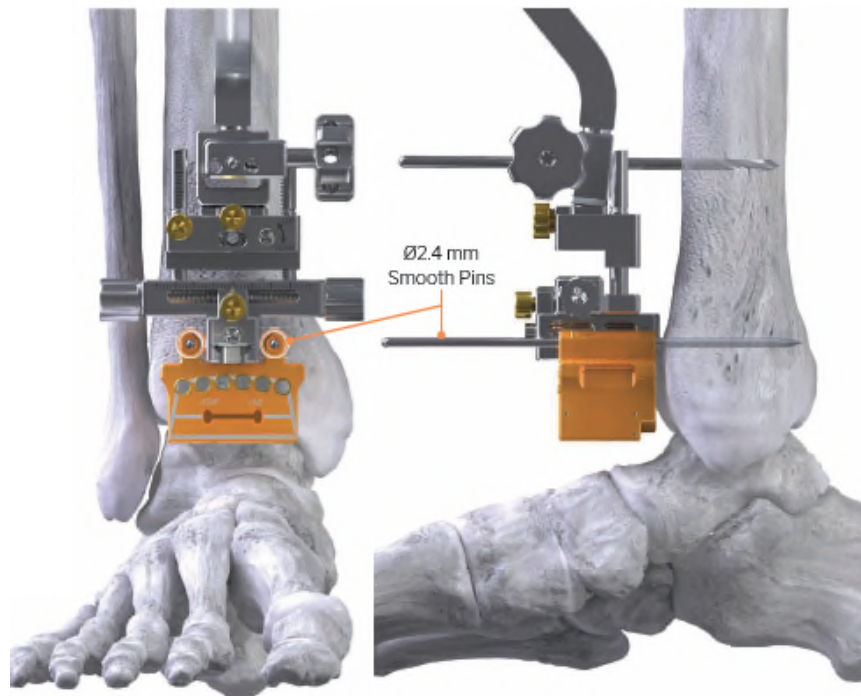
- Under an AP fluoroscopic view, evaluate and adjust:
 - Sizing, then swap blocks to adjust as necessary, then lock the associated silver dovetail screw.
 - Medial/Lateral alignment, then secure position by locking the associated gold screw.
 - Joint line height against interoperative anatomic landmarks, then secure position by locking the associated gold screw.

**SURGICAL NOTE:**

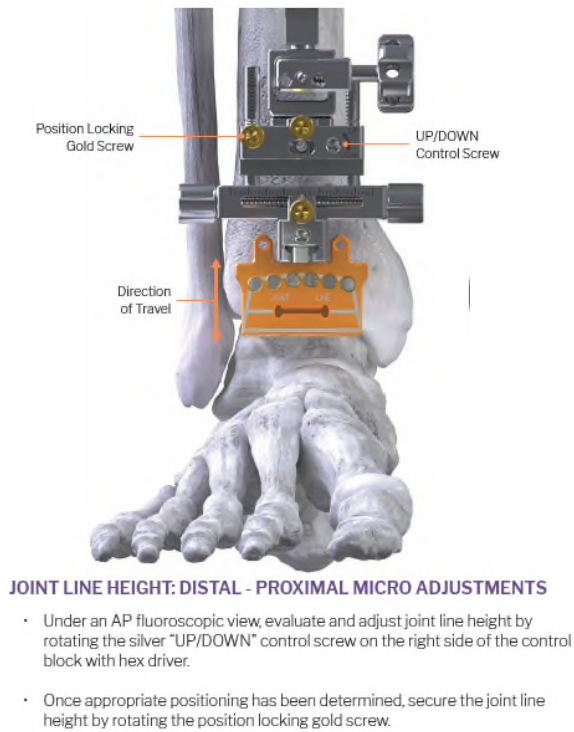
Radiopaque alignment markers within the Sizing Resection Block are used to evaluate appropriate size, joint line positioning and medial / lateral position within tibiotalar joint.

(Ex. 5, FasTrac Surgical Technique Guide, at 10.)

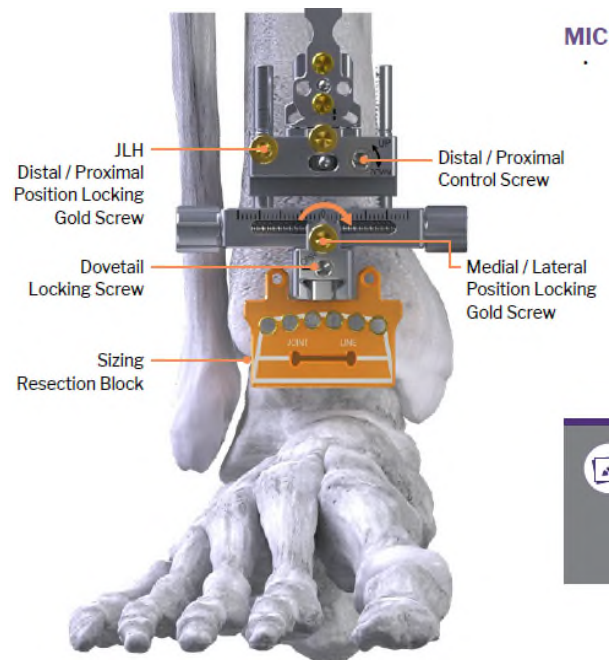
81. The APEX 3D System includes “the frames comprising: a first frame releasably secured to at least one fixation pin configured to project outwardly from an anterior surface of a bone located adjacent to the joint, the first frame being coupled to a first threaded shaft so that upon turning the first threaded shaft, the first frame is movable to effect a proximal-distal position adjustment of the tool.” For example, as depicted and described in the APEX 3D Surgical Technique Guides:



(Ex. 3, APEX 3D System Surgical Technique Guide, at 13.)



(Ex. 3, APEX 3D System Surgical Technique Guide, at 11.)

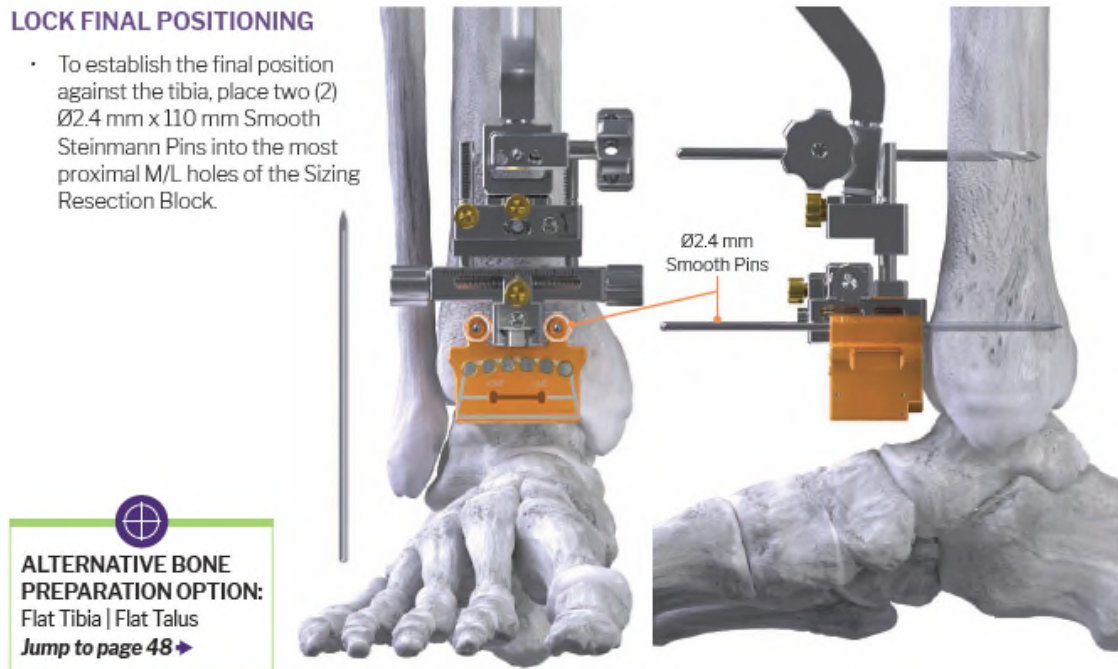


(Ex. 5, FasTrac Surgical Technique Guide, at 10.)

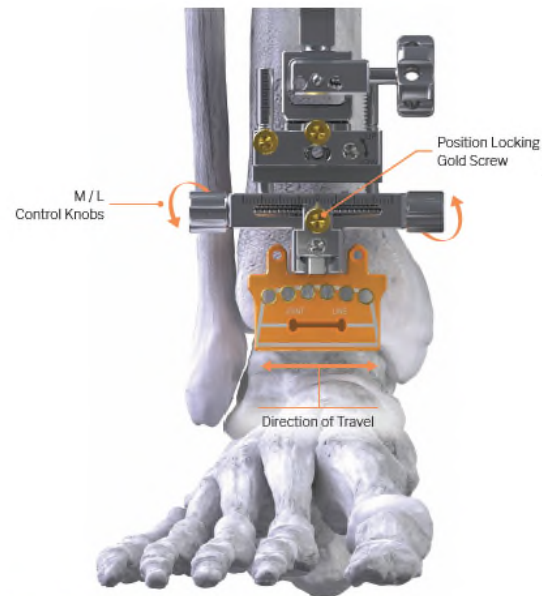
82. The APEX 3D System includes “a second frame secured to the first frame, the second frame being coupled to a second threaded shaft so that upon turning the second threaded shaft, the second frame is movable to effect a medial-lateral adjustment of the tool.” For example, as depicted and described in the APEX 3D Surgical Technique Guides:

LOCK FINAL POSITIONING

- To establish the final position against the tibia, place two (2) Ø2.4 mm x 110 mm Smooth Steinmann Pins into the most proximal M/L holes of the Sizing Resection Block.



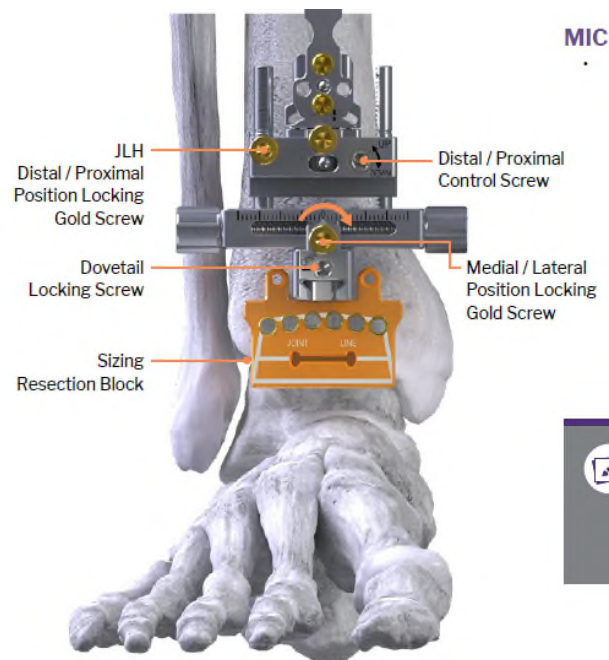
(Ex. 3, APEX 3D System Surgical Technique Guide, at 13.)



MEDIAL - LATERAL MICRO ADJUSTMENTS

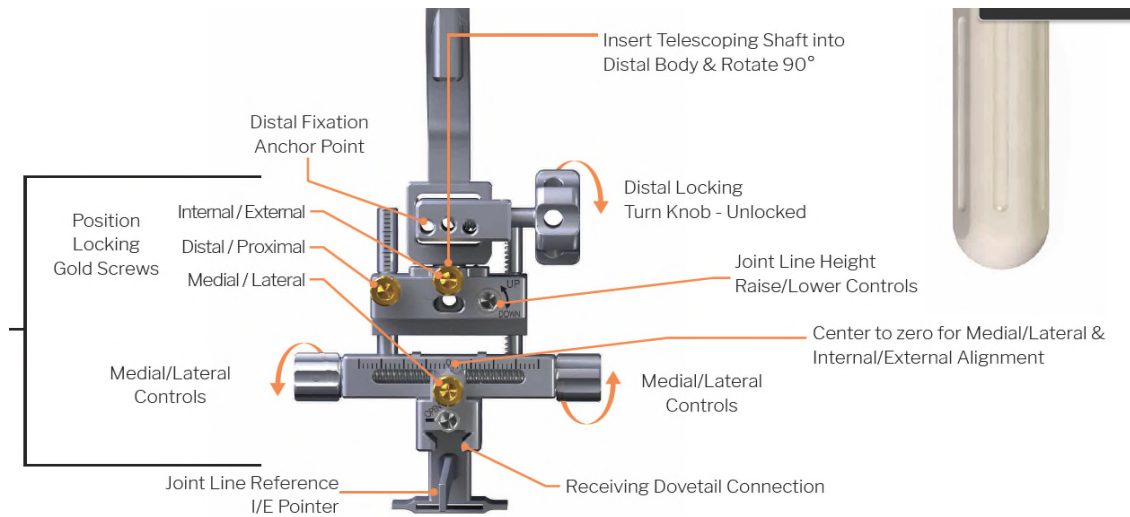
- Adjust medial / lateral (M/L) alignment by rotating the Distal Control Knobs.
- Use an AP fluoroscopic view to verify the Sizing Resection Block is aligned with the medial and lateral gutters.
- Lock in M/L alignment by rotating the center most gold screw until threads are fully seated.

(Ex. 3, APEX 3D System Surgical Technique Guide, at 12.)

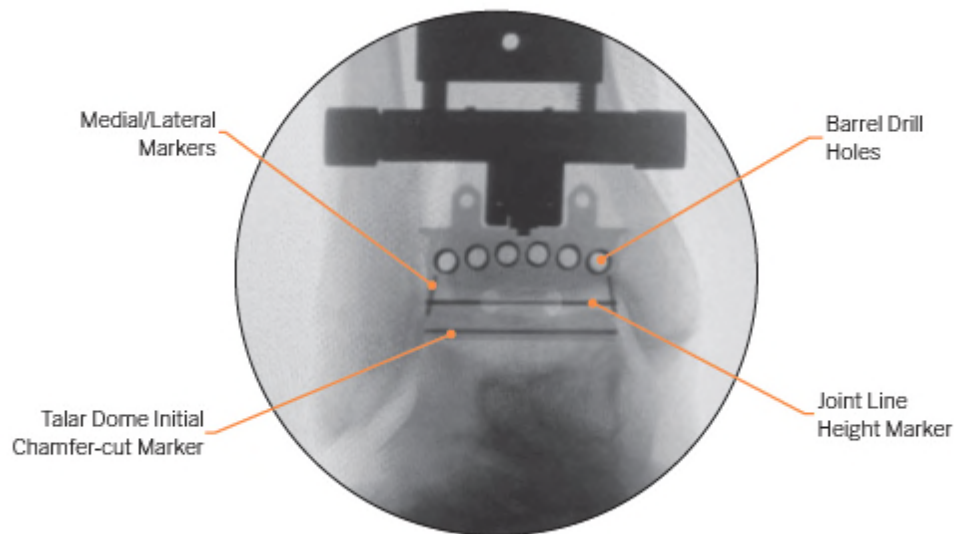


(Ex. 5, FasTrac Surgical Technique Guide, at 10.)

83. The APEX 3D System includes “a guide coupled to each of the frames so as to be located adjacent to the joint and positionable relative to the bone with reference to a radiopaque line located on the guide.” For example, as depicted and described in the APEX 3D Surgical Technique Guides:



(Ex. 3, APEX 3D System Surgical Technique Guide, at 8.)



(Ex. 3, APEX 3D System Surgical Technique Guide, at 8.)

JOINT LINE HEIGHT: DISTAL - PROXIMAL MICRO ADJUSTMENTS

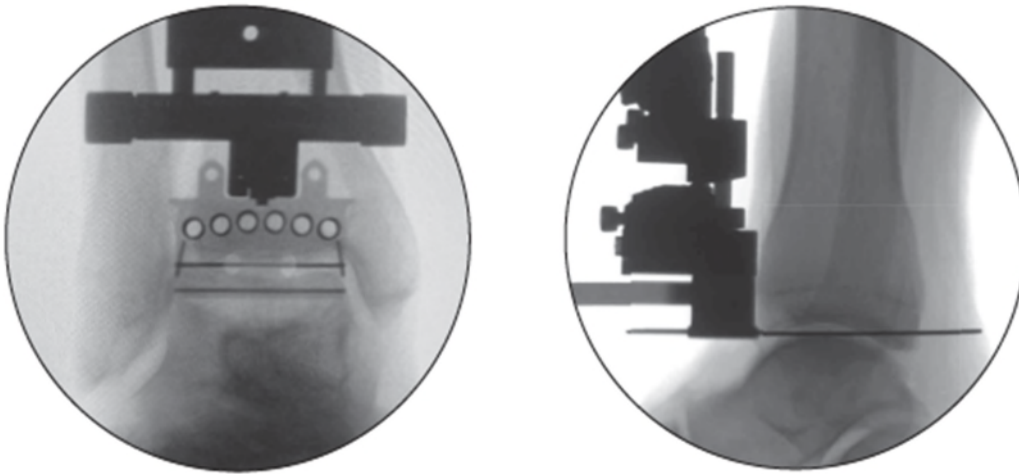
- Under an AP fluoroscopic view, evaluate and adjust joint line height by rotating the silver "UP/DOWN" control screw on the right side of the control block with hex driver.
- Once appropriate positioning has been determined, secure the joint line height by rotating the position locking gold screw.

(Ex. 3, APEX 3D System Surgical Technique Guide, at 11.)

MEDIAL - LATERAL MICRO ADJUSTMENTS

- Adjust medial / lateral (M/L) alignment by rotating the Distal Control Knobs.
- Use an AP fluoroscopic view to verify the Sizing Resection Block is aligned with the medial and lateral gutters.
- Lock in M/L alignment by rotating the center most gold screw until threads are fully seated.

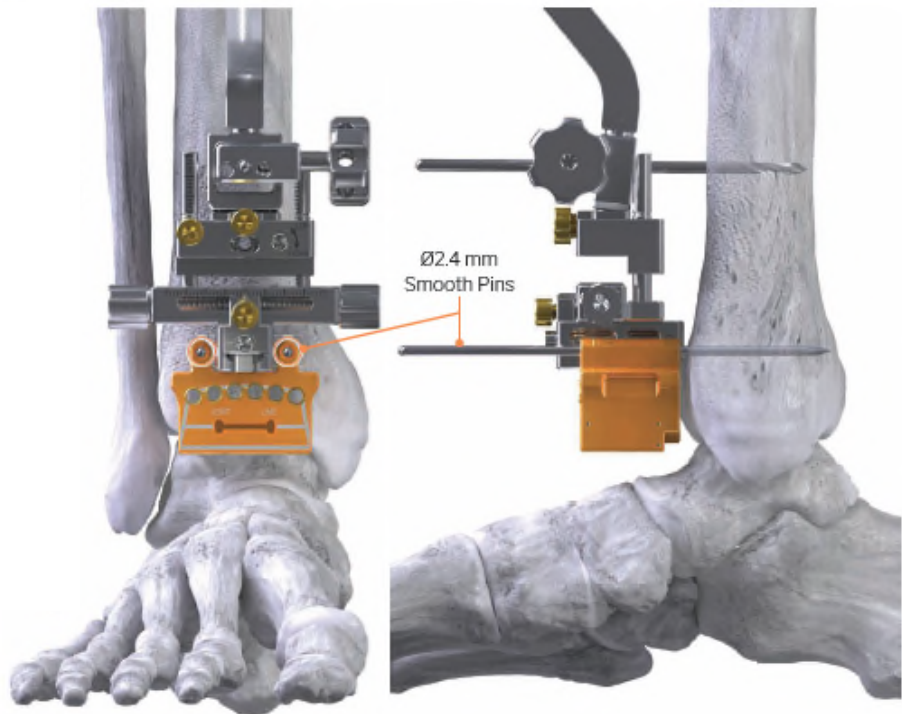
(Ex. 3, APEX 3D System Surgical Technique Guide, at 12.)



FINALIZE ALIGNMENT

- Confirm all planes of alignment visually and under fluoroscopy.
- Make final adjustments as necessary

(Ex. 3, APEX 3D System Surgical Technique Guide, at 13.)



(Ex. 3, APEX 3D System Surgical Technique Guide, at 13; *see* Ex. 4, Maven Surgical Technique Guide, at 9; Ex. 5, FasTrac Surgical Technique Guide, at 8-11.)

84. Defendant Paragon 28 also has indirectly infringed and continues to indirectly infringe at least Claims 1-6 and 8-11 of the 336 patent by inducing infringement pursuant to 35 U.S.C. § 271(b) and/or contributing to infringement pursuant to 35 U.S.C. § 271(c).

85. On information and belief, Defendant Paragon 28's customers directly infringe the 336 patent. For example, when the APEX 3D System is sold to Paragon 28's customers, such as hospitals and doctors, those customers infringe at least claims 1-6 and 8-11 of the 336 Patent through the use of the APEX 3D System.

86. On information and belief, Paragon 28 has directed and directs third parties, including customers and other users, in the United States, to use the APEX 3D System, which directly infringe the 336 Patent and which Paragon 28 knows infringes the 336 patent. Defendant

provides instructions to third parties including customers, such as hospitals and doctors, on how to use the accused APEX 3D System in a manner that Paragon knows practices the claimed inventions. For example, as described above, Defendant's instructions for use and surgical technique guides describe how to use the APEX 3D System. The instructions for use and surgical technique guides highlight the infringing features to customers, such as hospitals and doctors. Example surgical technique guides and instructions for use are attached to this Complaint as Exhibits 3-5.

87. On information and belief, in violation of 35 U.S.C. § 271(b), Defendant Paragon 28 specifically intends to induce infringement of the 336 patent by its customers and users of the APEX 3D System and has knowledge that the inducing acts would cause infringement or was willfully blind to the possibility that their inducing acts would cause infringement.

88. On information and belief, at all relevant times, Defendant Paragon 28 knew or was willfully blind to how the APEX 3D System infringes the 336 Patent. Paragon 28 has been and is actively inducing infringement of the 336 Patent by actively and knowingly inducing third parties such as customers, including, e.g., hospitals and doctors, to commit acts that Defendant knows constitute infringement of the 336 Patent.

89. On information and belief, Defendant Paragon 28 actively and knowingly intended to aid, abet, direct, encourage, or otherwise instruct such third parties by Paragon 28's offer for sale and sale of the APEX 3D Systems and instructions to infringe the 336 patent. Paragon 28 encourages infringement by customers at least by providing product instructions for use and surgical technique guides, as discussed above, that instruct users on how to use the APEX 3D System in an infringing manner. Paragon 28 has and continues to specifically intend to induce infringement of the 336 Patent.

90. On information and belief, despite Paragon 28's knowledge of the 336 Patent and knowledge that customers will necessarily infringe the 336 Patent when the APEX 3D System is used as instructed, Paragon 28 has and continues to encourage infringement.

91. Defendant Paragon 28 also contributes to infringement of the 336 Patent by Paragon 28's customers in violation of 35 U.S.C. §271(c). On information and belief, Paragon 28 was aware of the 336 Patent at all relevant times, as discussed above. Paragon 28 sells and offers for sale within the United States the APEX 3D System knowing that it constitutes a material part of the claimed inventions of the 336 Patent, knowing that the APEX 3D System is especially made or especially adapted for use in infringing the 336 Patent, and knowing that the APEX 3D System is not a staple article or commodity of commerce suitable for substantial non-infringing use.

92. Unless enjoined by this Court, Defendant Paragon 28 will continue to infringe the 336 Patent and as a direct result Wright Medical will continue to suffer harm, including irreparable harm for which there is no adequate remedy at law. Accordingly, Wright Medical is entitled to injunctive relief against such infringement pursuant to 35 U.S.C. § 283.

93. Wright Medical has suffered and will continue to suffer damage as a direct and proximate result of Defendant Paragon 28's infringement of the 336 Patent. Thus, in addition to injunctive relief, Wright Medical is entitled to recover damages for such infringement pursuant to 35 U.S.C. § 284 in an amount to be proven at trial.

94. On information and belief, the infringement of the 336 Patent by Defendant Paragon 28 has been and continues to be willful and deliberate.

95. Defendant Paragon 28 has committed and continues to commit all of the above acts of infringement without license or authorization from Wright Medical.

96. On information and belief, Defendant Paragon 28 has had knowledge of the 336 Patent and knowledge that the APEX 3D System is covered by the 336 Patent. Paragon 28 has copied and made, offered for sale and sold the APEX 3D System knowing of the risk of infringement and/or in view of a risk of infringement that was sufficiently obvious that it should have been known to Paragon 28. Paragon 28's infringing actions have been and continue to be willful, entitling Wright Medical to increased damages under 35 U.S.C. § 284.

97. Defendant Paragon 28's egregious conduct justifies an increase of three times the damages to be assessed pursuant to 35 U.S.C. § 284, and further qualifies this action as an exceptional case supporting an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

DEMAND FOR JURY TRIAL

Wright Medical demands a trial by jury under Rule 38 of the Federal Rules of Civil Procedure of all issues in this action so triable.

PRAYER FOR RELIEF

WHEREFORE, Wright Medical prays for judgment in its favor against Defendant Paragon 28:

A. a judgment adjudging Paragon 28 to have infringed each of the Asserted Patents under 35 U.S.C. §§ 271(a), (b) and/or (c);

B. an award of damages sustained as a result of Paragon 28's infringement of the Asserted Patents in an amount to be determined at trial as provided under 35 U.S.C. § 284 that is adequate to compensate Wright Medical for Paragon 28's infringement;

C. an order that Paragon 28 and each of its officers, employees, agents, attorneys, all of its parent, subsidiary, and affiliate corporations, other of its related business entities, and any persons in active concert, participation or in privity with one or more of the foregoing, and each

of their successors and assigns, be permanently restrained and enjoined from continued acts of infringement of the Asserted Patents;

D. an order trebling of damages pursuant to 35 U.S.C. § 284 as a result of Paragon 28's willful infringement;

E. a finding adjudging that this is an exceptional case under 35 U.S.C. § 285;

F. an award to Wright Medical of its costs and attorneys' fees and expenses in this action, as provided by 35 U.S.C. § 285;

G. an accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales;

H. an award of pre-judgment and post-judgment interest and costs; and

I. such other relief as this Court may deem proper and just under the circumstances.

OF COUNSEL:

Robert A. Surrette

Wilhelm L. Rao

Ryan J. Pianetto

Jenna E. Saunders

MCANDREWS, HELD & MALLOY, LTD.

500 West Madison Street

Chicago, Illinois 60661

(312) 775-8000

Chris Lind

Mark L. Levine

Nevin M. Gewertz

BARTLIT BECK LLP

54 West Hubbard Street

Chicago, IL 06254

(312) 494-4400

December 23, 2021

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jack B. Blumenfeld (#1014)

Jeremy A. Tigan (#5239)

1201 North Market Street

P.O. Box 1347

Wilmington, DE 19899

(302) 658-9200

jblumenfeld@morrisnichols.com

jtigan@morrisnichols.com

*Attorneys for Plaintiff Wright Medical
Technology, Inc.*